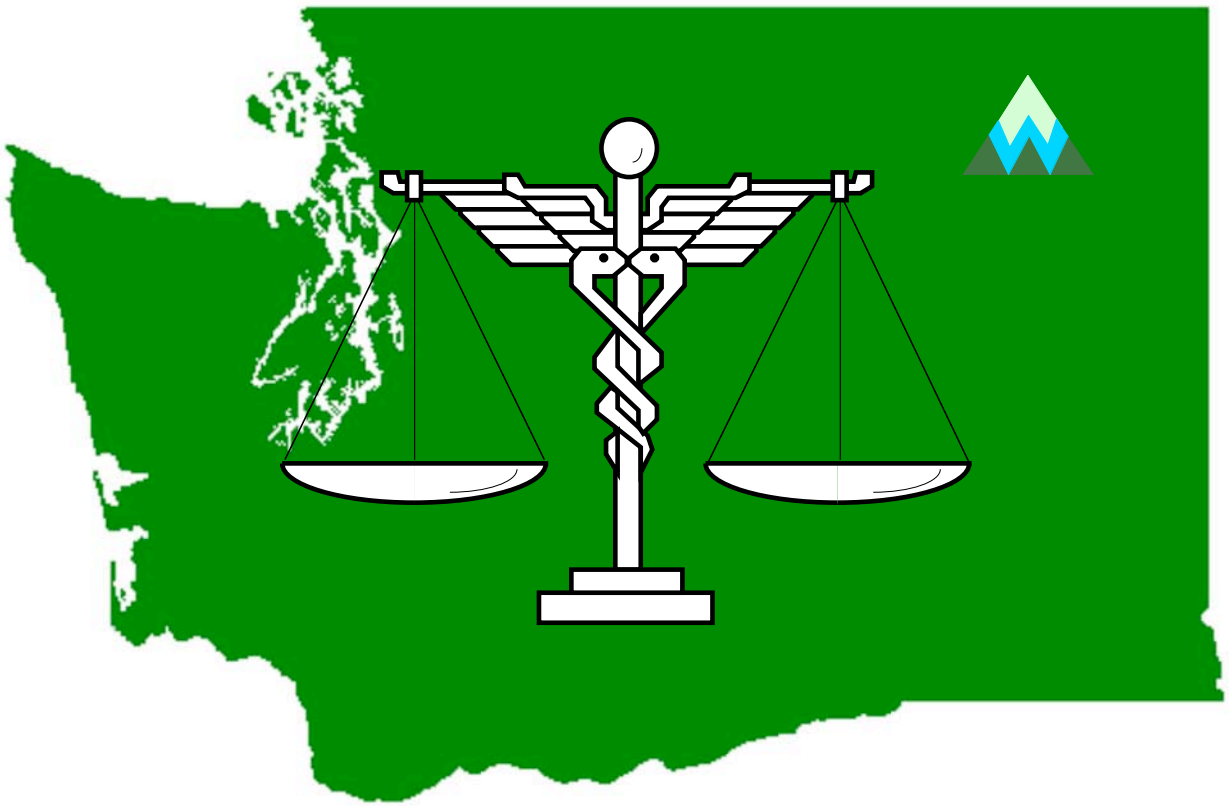
Washington State Certificate of Need Program Task Force Report



November 1, 2006

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Washington State
Certificate of Need Task Force

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November 1, 2006

The Honorable Christine Gregoire
Washington State Governor
Legislative Building
P.O. Box 40002
Olympia, WA 98504-0002

Mr. Thomas Hoemann
Secretary of the Senate
Washington State Senate
P.O. Box 40482
Olympia, WA 98504-0482

Mr. Rich Nafziger
Chief Clerk of the House
House of Representatives
P.O. Box 40600
Olympia, WA 98504-0600

Dear Governor Gregoire, Mr. Hoemann, and Mr. Nafziger:

The Washington State Certificate of Need Task Force is pleased to submit our final report to you on the Certificate of Need Program as directed by Engrossed Second Substitute House Bill 1688, chapter 282, Laws of 2005, as follows:

> *(2) A task force is created to study and prepare recommendations to the governor and the legislature related to improving and updating the certificate of need program in chapter 70.38 RCW. The report must be submitted to the governor and appropriate committees of the legislature by November 1, 2006.*

The Task Force and I will be glad to address any questions you may have concerning this final report. The report evaluates the Certificate of Need Program and recommends ways in which it can be improved.

Sincerely,

Carolyn Watts, PhD, Chair
Certificate of Need Task Force

Enclosure

cc: Senator Margarita Prentice, Chair, Senate Ways & Means Committee
Senator Joseph Zarelli, Ranking Minority Member, Senate Ways & Means Committee
Senator Karen Keiser, Chair, Senate Health & Long-Term Care Committee
Senator Alex Deccio, Ranking Minority Member, Senate Health & Long-Term Care Committee
Senator Linda Evans Parlette, Vice Chair, Joint Legislative Audit and Review Committee
Senator Phil Rockefeller, Asst. Secretary, Joint Legislative Audit and Review Committee
Representative Helen Sommers, Chair, House Appropriations Committee
Representative Gary Alexander, Ranking Minority Member, House Appropriations Committee and Secretary, Joint Legislative Audit and Review Committee
Representative Eileen Cody, Chair, House Health Care Committee
Representative Bill Hinkle, Ranking Minority Member, House Health Care Committee
Representative Ross Hunter, Chair, Joint Legislative Audit and Review Committee
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Jon Smiley ..... Health Care Provider Representative; CEO, Sunnyside Community Hospital
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Task Force Report

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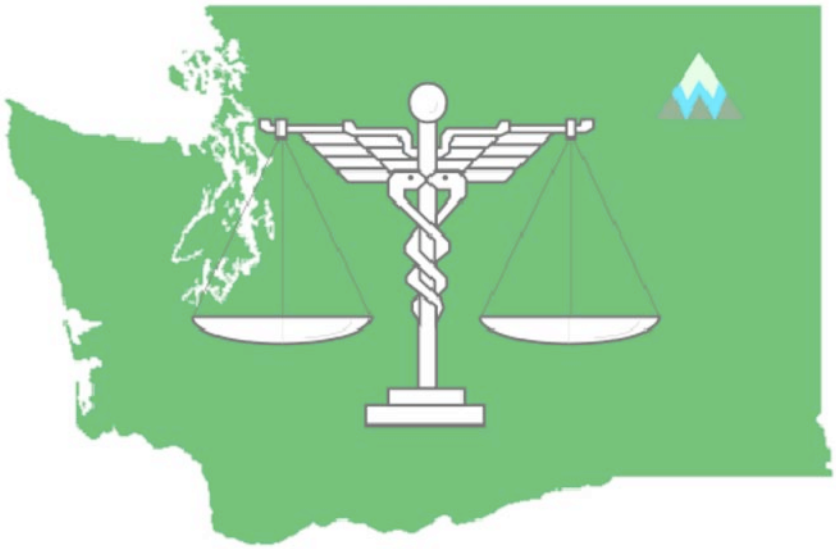


Washington State Certificate of Need Program
Task Force Report
Executive Summary

Introduction

This report provides recommendations to improve and strengthen the Certificate of Need (CON) Program in the State of Washington. It was produced in response to legislation passed in the 59th Regular Session of the Washington State Legislature as Engrossed Second Substitute House Bill (ESSHB) 1688. The bill created a Task Force (TF) with representation from groups affected by the existing CON Program and those interested in health care planning. The TF was directed to submit its report to the Governor and Legislature by November 1, 2006.

The TF was guided in its work by the principles of its enabling statute, ESSHB 1688. Those principles, as stated in Section 3(1), were:

(a) The supply of a health service can have a substantial impact on utilization of the service, independent of the effectiveness, medical necessity, or appropriateness of the particular health service for a particular individual;
(b) Given that health care resources are not unlimited, the impact of any new health service or facility on overall health expenditures in the state must be considered;
(c) Given our increasing ability to undertake technology assessment and measure the quality and outcomes of health services, the likelihood that a requested new health facility, service, or equipment will improve health care quality and outcomes must be considered; and
(d) It is generally presumed that the services and facilities currently subject to certificate of need should remain subject to those requirements.

Compelling forces provide the context for the recommendations contained in this report. Health care expenditures are rising at rates substantially above the national annual rate of inflation, while an increasing number of individuals do not have access to affordable health care. Further, studies indicate that the quality of care received by those who do have access is often uneven, with measurable differences in practice patterns across regions and facilities. Many believe that market forces cannot by themselves control expenditures on health care services, particularly because existing regulatory and legal structures constrain payers in their ability to limit utilization, and because there is so little transparency in health care markets. Market forces alone are also not likely to increase access to low income individuals or significantly improve quality of care.

Considerations of expenditure control, financial access, and quality are not the only issues of importance in health care markets. Non-financial barriers to access (e.g., geography, traffic, and population concentrations) can be significant. Public health priorities, including disaster preparedness, are not included in private market transactions. As a result, the stability of the health care delivery system may have value beyond that attributed to it by purely market forces.

The TF offers the recommendations in this report in the belief that CON must be conducted in the context of a comprehensive, strategic state health plan built on a foundation of adequate data, and arising from a transparent decision-making process. To be effective and persuasive, the state health plan must include mechanisms for monitoring and evaluation, be funded at a level that

allows participating state agencies to adequately respond, and be regularly reviewed and updated. Further, the TF believes that CON regulations flowing from this strategic health plan should apply equally to similar services delivered in different settings.

The TF is cognizant of the magnitude of this undertaking, but feels it is essential to guide a CON Program that can contribute to the goals of increased access, expenditure control, and improved outcomes. While it recognizes that no single policy tool can adequately address the complex policy problems in the health care industry, the TF believes that the recommendations of this report will improve and strengthen the CON Program in the state of Washington.

CON Purpose Recommendations

The TF recommends that a designated state agency, the Governor's office, or other public body undertake a biennial strategic health planning process. This planning process would factor in specific quality criteria and population health indicators, and would coordinate the efforts of various state agencies including those tasked with licensure, reimbursement, and data systems. The state health plan would be concerned with the stability of the health system, encompassing health care financing, services, quality, and the availability of information and services for all residents.

The TF recommends that the state health plan include the following components: rationale, participants, description of the existing health system, description of the desired health system, action plan for implementation, evaluation methods, and definitions. The plan must provide attention to expenditure control, and integrate criteria for evidence-based medicine into the planning process.

The TF recommends that both consumers and providers throughout the state be involved in the health planning process. Desired outcomes should be clearly articulated and available for public review. The TF views the CON Program as a component of the state health plan that would contribute to its public policy goals. The CON Program's purpose is to facilitate access to quality care at a reasonable cost for all residents, encourage optimal use of existing health care resources, foster expenditure control, support quality improvement efforts, and prevent unnecessary duplication of health care facilities, medical equipment and health services.

The TF also recommends that an expanded and independently funded data system support the review and monitoring of the health care facilities, medical equipment and health services regulated by the CON Program. There must be regular evaluation of the impact of the CON Program on health care expenditures, access, quality, and innovation.

Review Process Recommendations

With regard to the scope of CON review, the TF recommends the expansion of the criteria used to determine which facilities and services are regulated. Any tertiary service whose clinical quality and/or cost effectiveness is directly and demonstrably tied to volume is recommended for inclusion, as is any new service that may have a significant adverse impact on the existing health delivery system within a particular service area. The TF recommends that inconsistent state regulation of any health care facility, service, or major medical equipment based on ownership or

Medicare certification be eliminated. Emerging or existing devices, technology, and services for which efficacy, safety, and utilization have not been fully established are recommended for inclusion.

The TF recommends the continued CON review of those facilities, equipment, and services currently subject to CON review. The TF also recommends an expansion of CON regulation to the following facilities and services: cyber knives, gamma knives, positron emission tomography scanners (including computed tomography scanner combinations), linear accelerators, robotic surgery, freestanding emergency departments, freestanding radiological service centers, diagnostic imaging centers, oncology (cancer) treatment centers, cardiac surgery suites, and all ambulatory surgery centers.

The TF recommends further study of the concept of financial thresholds, and the study of the following facilities and services to determine if CON review is warranted: acute care bed conversions, long-term care bed conversions, magnetic resonance image scanners, diagnostic cardiac catheterization, physician office-based surgery, research and demonstration projects, air ambulances, and non-Medicare certified home health care and hospice agencies. At this time, the TF further recommends against the application of new financial review thresholds to any reviewed facility, equipment, or service. All facilities and services reviewed under the CON Program must be licensed or certified, with data reporting linked to CON data systems.

The TF recommends that criteria for the review of specific applications include: community need for the proposed services, impact on the current health system infrastructure, ability of existing providers to serve the underinsured and uninsured, provisions for charity care, availability of an appropriate workforce, and agreement to provide services to Medicaid and Medicare enrollees. The CON Program must be conducted in as transparent and accountable a manner as possible. Finally, the TF recommends that the criteria, standards, and methods used to determine need be reviewed and updated at least biennially, in consultation with a technical advisory committee.

Program Operations Recommendations

The TF recommends added funding, data, and compliance mechanisms to improve CON processes. The TF also recommends that the length of time during which approved projects must be monitored and held accountable be extended to at least five years after project completion. Penalties for non-compliance with the provisions and conditions of the approved application should be created and enforced. Examples of appropriate penalties include, but need not be limited to, significant fines, revocation of the CON award, moratorium on future CON applications for a specified period, and/or revocation of license.

The TF recommends that the state collect and report data from the CON process on an ongoing basis using consistent and reliable performance measures. The data for CON analysis and monitoring are to be a subset of a comprehensive data system created for state health planning. This data system shall have data collection and reporting methods consistent with current technology. Data elements are to include inpatient and outpatient utilization and outcomes measures, and financial and utilization information related to charity care, quality, and cost, regardless of the service location. This information shall be available for applicants and others, including the state health planning body, other appropriate agencies, and the public.

A fee structure for CON applications, supplemented with other sources of revenue sufficient to cover the direct costs of CON review, monitoring, and other related costs (e.g., data systems), is needed. The TF recommends the enhancement of communication and improved coordination among affected state agencies, the retention of periodic progress reports, and expansion of monitoring systems as data capabilities permit.

The TF recommends changes to the CON Program to allow expedited and/or abbreviated review cycles, invited CON proposals based on service needs as determined by the state health plan, and use of evidence-based health care criteria and standards. The consistency of review across analysts must be assured, and a more efficient electronic application process that is transparent through all its phases must be maintained.

Background

Statutory Guidance

This report is produced as a result of specific legislation passed in the 59th Regular Session of the Washington State Legislature. Engrossed Second Substitute House Bill (ESSHB) 1688 was signed by Governor Christine O. Gregoire and enacted as Chapter 282, Laws of 2005. In Section 1 of the bill, the Legislature found that:

(1) Since the enactment of health planning and development legislation in 1979, the widespread adoption of new health care technologies has resulted in significant advancements in the diagnosis and treatment of disease, and has enabled substantial expansion of sites where complex care and surgery can be performed;

(2) New and existing technologies, supply sensitive health services, and demographics have a substantial effect on health care expenditures. Yet, evidence related to their effectiveness is not routinely or systematically considered in decision making regarding widespread adoption of these technologies and services. The principles of evidence-based medicine call for comprehensive review of data and studies related to a particular health care service or device, with emphasis given to high quality, objective studies. Findings regarding the effectiveness of these health services or devices should then be applied to increase the likelihood that they will be used appropriately;

(3) The standards governing whether a certificate of need should be granted in RCW 70.38.115 focus largely on broad concepts of access to and availability of health services, with only limited consideration of cost-effectiveness. Moreover, the standards do not provide explicit guidance for decision making or evaluating competing certificate of need applications; and

(4) The certificate of need statute plays a vital role and should be reexamined and strengthened to reflect changes in health care delivery and financing since its enactment.

Work Groups

Section 2 of ESSHB 1688 created a Task Force (TF) representative of those with special interest in the CON Program, and health care planning and delivery in general. The Legislature specifically directed the TF to study and prepare recommendations to the Governor and the Legislature related to improving and updating the state of Washington CON Program described in chapter 70.38 RCW. The TF was further directed to submit its report to the Governor and appropriate committees of the Legislature by November 1, 2006. As specified, TF members were appointed by the Governor and served over a period of 12 months. The names and affiliations of TF members and TF meeting dates appear in Appendix A-1.

Section 2 of the legislation also assigned administration and support of this study to the Health Care Authority (HCA). A budget of $250,000 was provided in the operating appropriations to the agency [see Engrossed Substitute Senate Bill 6090, Section 213(9), enacted as Chapter 518, Laws of 2005 (partial veto)].

In accordance with Section 2(3), the TF established a Technical Advisory Committee (TAC) to conduct research, consider stakeholder perspectives and interests, and prepare recommendations

to present to the CON TF for consideration. The TAC met over a period of eight months. The names and affiliations of TAC members and TAC meeting dates appear in Appendix A-2.

Background Information

The work of both the TF and the TAC was guided by the following principles outlined in Section 3(1) of ESSHB 1688:

(a) The supply of a health service can have a substantial impact on utilization of the service, independent of the effectiveness, medical necessity, or appropriateness of the particular health service for a particular individual;

(b) Given that health care resources are not unlimited, the impact of any new health service or facility on overall health expenditures in the state must be considered;

(c) Given our increasing ability to undertake technology assessment and measure the quality and outcomes of health services, the likelihood that a requested new health facility, service, or equipment will improve health care quality and outcomes must be considered; and

(d) It is generally presumed that the services and facilities currently subject to certificate of need should remain subject to those requirements.

The recommendations of the TF were mandated to address at least a specific set of issues outlined in Section 3(2) of ESSHB 1688 (Appendix A-3). Thus, the TF sought to make recommendations that would:

- Promote the improvement of quality/outcomes of health care delivered in the state;
- Control the expenditures on health care delivered in the state; and
- Monitor the outcomes through a revised state health planning and development process.

The TF used a variety of resources in the preparation of this report, including:

- Input from interested parties at public meetings, and through written correspondence;
- Technical papers on a number of topics related to CON issues and operations;
- Analysis and input from a consultant familiar with CON programs in other states;
- Expert presenters and reports from organizations and interests in Washington and other states (see Appendices A-4, A-5, and A-6);
- Relevant reports from consulting firms; and
- The recently completed JLARC audit of the Washington State CON Program.

The TF also considered the suggestions of its TAC. The TAC reviewed existing statutory language, considered additional input and information regarding improvement to the CON Program, and proposed statutory changes and other recommendations to the TF.

The TF considered the TAC's proposals and adopted, amended, declined, or returned them to the TAC for further clarification or consideration. Not all TAC proposals are addressed in this report.

The minutes of the TF meetings and relevant materials will be posted on the Health Care Authority website http://www.hca.wa.gov/contf/ through June 30, 2007. They will be archived thereafter.

Preamble

The TF developed a Preamble as the foundation for the recommendations set forth in this report. This preamble describes the factors that the TF felt supported its recommendations.

Given that:

- Health care expenditures are rising at rates substantially above the annual national rate of inflation;
- Market forces alone cannot control health care expenditures;
- The current structure of the health care financing and delivery system distances recipients from the financial burden of their care and compromises their ability to make informed choices;
- Increasing numbers of Washingtonians are unable to pay for necessary health care because they are uninsured, underinsured, or not eligible for publicly funded programs such as Medicaid and Medicare;
- Published research supports the existence of a relationship between the quality of health care outcomes and volume for providers of selected services;
- Geography, traffic, and population concentrations create barriers to access;
- Public health issues, disaster preparedness, and other emergent health priorities matter and need to be considered in the planning process;
- Changes in the availability of health care services in a community can have unforeseen consequences;
- Existing regulatory and legal structures constrain the ability of health care payers in their ability to limit utilization of health care services;
- No single policy tool can adequately address the complex policy problems in the health care industry;
- There is so little transparency in health care markets; and
- CON regulations should apply equally to similar services delivered in different settings;

the TF submits the following report and recommendations to improve and strengthen the CON Program in chapter 70.38 RCW.

Recommendations

The final recommendations as approved by the TF are presented in the following sections. Supporting information appears in the Appendices.

Recommendations

1. Purpose and Goals

ESSHB 1688, Section 3(2) directs the TF to undertake:

(b) A review of the purpose and goals of the current certificate of need program, including the relationship between the supply of health services and health care outcomes and expenditures in Washington state;

After much discussion, the TF concluded that the CON Program would be most effective within the context of a broader state health planning process supported by an adequate data reporting system.

With this perspective, the TF recommends RCW 70.38.015 to read as follows. Specific changes may be seen in Appendix C-1.

It is declared to be the public policy of this state:

(1) That a strategic health planning process, responsive to changing health and social needs and conditions, is essential to the health, safety, and welfare of the people of the state. Such a process shall be reviewed and updated biennially by a designated state agency or body:
   (a) To promote, maintain, and assure the health of all citizens in the state;
   (b) To provide accessible health services through the maintenance of an adequate supply of health facilities and an adequate workforce;
   (c) To control excessive increases in costs;
   (d) To apply specific quality criteria and population health indicators;
   (e) To recognize prevention as a high priority in health programs;
   (f) To address periodic priority issues including disaster planning, public health threats, and public safety dilemmas; and
   (g) To coordinate efforts among state agencies including those tasked with facility, services, and professional provider licensure; state and federal reimbursement; health service utilization data systems; and others;

(2) That both consumers and providers throughout the state shall be involved in this health planning process, outcomes of which shall be clearly articulated and available for public review and use;

(3) That the CON Program is a component of a health planning regulatory process that:
   (a) Contributes to state health plan and public policy goals that are:
      (i) clearly articulated, and
      (ii) regularly updated;
   (b) Balances considerations of:
      (i) access to quality care at a reasonable cost for all residents,

(ii) optimal use of existing health care resources,
(iii) fostering of expenditure control, and
(iv) elimination of unnecessary duplication of health care facilities and services;

(c) Supports improved health care outcomes by:
(i) basing decisions on the best available evidence and information, and
(ii) continuously monitoring compliance;

(d) Is accountable for maintaining the resources necessary for high quality decisions that are timely and consistent; and

(e) Regularly evaluates the impact of capacity management on health service expenditures, access, quality, and innovation;

(4) That the development and ongoing maintenance of adequate health care information, statistics, and projections of need for health facilities and services are essential to effective health planning; at a minimum, available data shall support the review and monitoring of the specified health care facilities and services regulated by the CON Program;

(5) That the development of other approaches to health care expenditure control shall be considered, including the strengthening of competition; and

(6) That strategic health planning shall be concerned with the stability of the health system, encompassing health care financing, quality, and the availability of information and services for all residents.

A detailed table showing the TF's worksheet appears in Appendix C-1
(RCW 70.38.015 subsections 1, 2, 3, 4, 5, and 6).

2. Criteria for Review of CON Applications

ESSHB 1688, Section 3(2) directs the TF to examine:

(d) The criteria for review of certificate of need applications, as currently defined in RCW 70.38.115, with the goal of having criteria that are consistent, clear, technically sound, and reflect state law, including consideration of:

(i) Public need for the proposed services as demonstrated by certain factors, including, but not limited to:

(A) Whether, and the extent to which, the project will substantially address specific health problems as measured by health needs in the area to be served by the project;

(B) Whether the project will have a positive impact on the health status indicators of the population to be served;

(C) Whether there is a substantial risk that the project would result in inappropriate increases in service utilization or the cost of health services;

(D) Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and

(E) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project, including whether there is data to indicate that the proposed health services would constitute

innovations in high quality health care delivery;

(ii) Impact of the proposed services on the orderly and economic development of health facilities and health resources for the state as demonstrated by:

(A) The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;

(B) The impact of the project on the ability of existing affected providers and facilities to continue to serve uninsured or underinsured residents of the community and meet demands for emergency care;

(C) The availability of state funds to cover any increase in state costs associated with utilization of the project's services; and

(D) The likelihood that more effective, more accessible, or less costly alternative technologies or methods of service delivery may become available;

After considering the existing criteria for the review of CON applications, the TF modified and expanded the analytical provisions and added new criteria. The TF recommends that these criteria be reviewed and updated as needed, at least every two years.

The TF recommends stronger connections between CON and licensure of health care facilities and providers. Better communication between these two regulatory activities would enable the Department of Health to improve its monitoring and enforcement of those CONs issued with certain understandings or conditions. Similarly, the TF recommends that CON decisions take into more careful consideration the charity care obligations of health care facilities and providers. Understanding that charity care obligations apply at this time only to hospitals, the TF recommends language in RCW 70.38.115(2)(l) that would expand consideration of charity care programs and activities to other health care entities and providers.

With this perspective, the TF recommends RCW 70.38.115 to read as follows. Specific changes appear in Appendix C-4.

(1) Certificates of need shall be issued, denied, suspended, or revoked by the designee of the secretary in accord with the provisions of this chapter and rules of the department that develop review criteria and establish review procedures.

(2) Criteria for the review of CON applications, except as provided in subsection (3) of this section for health maintenance organizations, shall include, but not be limited to, consideration of the following:

(a) Community need for the proposed services based on current utilization data and trends;

(b) The availability of less costly or more effective alternative methods of providing such services;

(c) The financial feasibility and the probable impact of the proposal on the cost of and charges for providing health services in the community to be served, including the impact on the current health system infrastructure and ability of existing providers to serve the underinsured and uninsured;

(d) In the case of health services to be provided,

(i) the availability of alternative uses of project resources for the provision of other health services,
(ii) the extent to which such proposed services will be accessible to all residents of the area to be served,
(iii) the need for and the availability in the community of services and facilities for health care providers and their patients, and
(vi) the impact on existing and proposed institutional and other educational training programs for health practitioners at the student, internship, and residency training levels;

(e) In the case of a construction project, the costs and methods of the proposed construction, including the cost and methods of energy provision, and the probable impact of the project,
(i) on the cost of providing services by the applicant, and
(ii) on the cost of providing services by other entities;

(f) The special needs and circumstances of children's hospitals;

(g) Improvements or innovations in the financing and delivery of health services that foster cost containment and cost effectiveness, and/or promote quality;

(h) For proposed health services, a comparison of the efficiency and appropriateness of the use of similar existing services and facilities;

(i) For existing services or facilities, the quality of care provided by such services or facilities in the past;

(j) In the case of hospitals, whether the applicant meets or exceeds the regional average level of charity care as determined by the secretary, and whether the applicant has adopted policies consistent with the charity care and reporting requirement of RCW 70.170.060;

(k) For other CON regulated services, whether the applicant will provide for charity care commensurate with current community standards for the service(s) to be offered;

(l) The availability of appropriate health care workers to deliver the proposed service; and

(m) Whether the applicant agrees to provide services to Medicaid and Medicare enrollees and agrees to not discriminate against Medicaid and Medicare enrollees based upon their coverage.

(3) A CON application from a health maintenance organization or a health care facility that is controlled, directly or indirectly, by a health maintenance organization, shall be approved if:

(a) Approval of such application is required to meet the needs of the members of the health maintenance organization and of the new members that such organization can reasonably be expected to enroll; and

(b) The health maintenance organization is unable to provide, through services or facilities that can reasonably be expected to be available to the organization, its health services in a reasonable and cost-effective manner that is consistent with the basic method of operation of the organization, and that makes such services available on a long-term basis through its associated physicians and other health professionals; and

A health care facility, or any part thereof, to which a CON was issued under this subsection may not be sold or leased and a controlling interest in such facility or in a lease of such facility may not be acquired unless the department issues a CON approving the sale, acquisition, or lease.

(4) CON decisions shall be consistent with a state health plan that is updated at least biennially, except in emergency circumstances that pose a threat to the public health. The department may issue a conditional CON if it finds that the project is justified only under specific circumstances. The conditions shall directly relate to the project being reviewed. The conditions may be eliminated if it can be substantiated that the conditions are no longer valid and the elimination of such conditions would be consistent with the purposes of this chapter.

(5) Criteria adopted for review in accordance with subsection (2) of this section may vary according to the purpose for which the particular review is being conducted or the type of health service reviewed. Criteria, standards, and methods for determining need shall be reviewed and updated at least biennially after consultation with a technical advisory committee.

A detailed table showing the TF's worksheet appears in Appendix C-4 (RCW 70.38.115 subsections 1, 2, 3, 4, and 5).

3. Scope of Services and Facilities Subject to CON Review

ESSHB 1688, Section 3(2) directs the TF to examine:

(c) The scope of facilities, services, and capital expenditures that should be subject to certificate of need review, including consideration of the following:

(i) Acquisitions of major medical equipment, meaning a single unit of medical equipment or a single system of components with related functions used to provide medical and other health services;

(ii) Major capital expenditures. Capital expenditures for information technology needed to support electronic health records should be encouraged;

(iii) The offering or development of any new health services, as defined in RCW 70.38.025, that meets any of the following:

(A) The obligation of substantial capital expenditures by or on behalf of a health care facility that is associated with the addition of a health service that was not offered on a regular basis by or on behalf of the health care facility within the twelve-month period prior to the time the services would be offered;

(B) The addition of equipment or services, by transfer of ownership, acquisition by lease, donation, transfer, or acquisition of control, through management agreement or otherwise, that was not offered on a regular basis by or on behalf of the health care facility or the private office of a licensed health care provider regulated under Title 18 RCW or chapter 70.127 RCW within the twelve-month period prior to the time the services would be offered and that for the third fiscal year of operation, including a partial first year following acquisition of that equipment or service, is projected to entail substantial incremental operating costs or annual gross revenue directly attributable to that health service;

(iv) The scope of health care facilities subject to certificate of need requirements, to include consideration of hospitals, including specialty hospitals, psychiatric hospitals, nursing facilities, kidney disease treatment centers including

freestanding hemodialysis facilities, rehabilitation facilities, ambulatory surgical facilities, freestanding emergency rooms or urgent care facilities, home health agencies, hospice agencies and hospice care centers, freestanding radiological service centers, freestanding cardiac catheterization centers, or cancer treatment centers. "Health care facility" includes the office of a private health care practitioner in which surgical procedures are performed;

The TF concluded that specific descriptive criteria were needed to evaluate whether additional health care services or facilities, or major medical equipment would require CON review. The TF recommendation related to scope of coverage is based on an examination of the facilities and services currently subject to review, as well as clarifying information and other recommendations from the TAC (see Appendix B-1) and comments from various stakeholders.

Review Criteria

The TF recommends that, if one or more of the following conditions exist, health care facilities, medical equipment, or health services shall be added to the current list of items subject to CON review:

- Tertiary services whose clinical quality and/or cost effectiveness is directly and demonstrably tied to volume, including high-risk tertiary services that require complex multi-specialty interactions;
- New, additional, or changed services that may have a significant adverse impact on the existing health delivery systems' ability to continue to provide essential services to all residents in an economically feasible manner, or that may impose significant barriers to access;
- New or existing health care facilities, health services, or major medical equipment for which there is inconsistent state regulation based on ownership or Medicare certification;
- Emerging or existing devices, technology, and services for which clinical efficacy and patient safety have not been fully established; and
- Emerging or existing devices, technology, and services for costly procedures whose appropriate utilization has not been established, and for which there is a risk of inappropriate utilization.

Modifications to Scope

On the basis of these criteria, the TF recommends the following modifications to the current scope of facilities, equipment, and services subject to CON review. These recommendations are presented in four categories:

- *Proposed for No Review:* items that would not require CON examination;
- *Proposed for Continued Review:* items that are currently reviewed by CON and would continue to be reviewed;

- *Proposed for New Review:* items not currently reviewed by CON, but recommended to be added; and
- *Proposed for Future Study:* items currently not reviewed that have been suggested for potential review, but require additional evaluation before a decision is made.

Appendix B-2 summarizes the TF recommendations. Appendix B-3 presents the worksheet the TF used to determine whether CON review is appropriate under the recommended criteria. Appendices C-2 (RCW 70.38.025 subsections 6 and new) and C-3 (RCW 70.38.105 subsections 4 and new) present the TF's worksheets that provide examples of how the recommendations could be applied to existing statutes.

Proposed for No Review

Long Term Care

Boarding homes (assisted living facilities)
Specialty care assisted living facilities
Intermediate care mentally retarded facilities
Residential care facilities
Psychiatric residential treatment facilities
Adult family homes

Medical Equipment

Hyperbaric chambers
Ultrasound machines
Heart-lung bypass machines
Computed tomography scanners

Outpatient Services

Behavioral health services
Opiate replacement treatment facilities (methadone treatment)
Urgent care facilities
Substance abuse services
Community clinics

Procedures

Primary/emergent angioplasty
Lithotripsy

Other Services

Information technology needed to support electronic health records
Medical office buildings
Birthing centers

Proposed for Continued Review

(NOTE: Some items were evaluated pursuant to the direction of ESSHB 1688, but are already reviewed as part of CON hospital review.)

Acute Inpatient

Substance abuse (adult – as part of overall hospital review)
Substance abuse (child/adolescent – as part of overall hospital review)

Intensive care units (ICU)/critical care units (as part of overall hospital review)
Adult ICU units (as part of overall hospital review)
Medical-surgical licensed beds
Rehabilitation beds (Level I)
Psychiatric beds (licensed)
Obstetrics (Levels II & III)
Pediatrics (specialty) – includes ICU
Neonatal ICU (Levels II & III)
Burn units (specialty)
Specialty hospitals (heart, orthopedic, surgical)

Long Term Care

Sub-acute care units (Medicare distinct part)
Long term care hospitals
Nursing homes
Continuing care retirement centers (5-year Medicaid life care requirement)
Swing beds (>5 beds)

Procedures

Therapeutic cardiac catheterization
Elective angioplasty
Kidney treatment centers (including hemodialysis)

Surgery

General inpatient (as part of overall hospital review)
Hospital outpatient (as part of overall hospital review)
Hospital-based ambulatory surgery centers (as part of overall hospital review)
Open heart (adult)
Open heart (pediatric)
Solid organ transplants (adult)
Solid organ transplants (pediatric)
Bone marrow/stem cell transplants
Freestanding ambulatory surgery centers open to non-owner practitioners

Other Services

Home health agencies (Medicare/Medicaid)
Hospice care centers (facilities)
Hospice agencies (Medicare/Medicaid)

Proposed for New Review

(NOTE: See Appendix B-3 for TF rationale supporting recommendations.)

Medical Equipment

Cyber knives
Gamma knives
Positron emission tomography scanners
Positron emission tomography/computed tomography scanners
Linear accelerators
Robotic surgery

Outpatient services

Freestanding emergency departments
Freestanding radiological service centers
Diagnostic imaging centers
Oncology (cancer) treatment centers

Surgery

Cardiac surgery suites (outpatient and not done under a hospital license)
All ambulatory surgery centers regardless of owner or operator
(NOTE: The current rule provides an exemption for single-specialty freestanding ambulatory surgery centers restricted to owner practitioners.)

Proposed for Future Study

Acute Inpatient

Conversion of acute care beds

Long Term Care

Conversion of long-term care beds

Medical Equipment

Magnetic resonance image scanners

Procedures

Diagnostic cardiac catheterization

Surgery

Physician practice office-based surgery

Other Services

Research and demonstration projects
Air ambulances
Home health agencies (regardless of payment source)
Hospice agencies (regardless of payment source)

Financial Thresholds

The TF recommends that no new financial review thresholds be applied to any facility, equipment, or service at this time. The TF concluded that the existing and new criteria (not merely the financial cost) serve to determine whether a facility, equipment, or service is subject to CON review.

4. New and Updated Service and Facility Specific Policies

ESSHB 1688, Section 3(2) directs the TF to examine:

(a) The need for a new and regularly updated set of service and facility specific policies that guide certificate of need decisions;

With this perspective, the TF recommends RCW 70.38.015 to read as follows. Specific changes appear in Appendix C-1.

It is declared to be the public policy of this state:

(3) That the CON Program is a component of a health planning regulatory process that:

(f) Utilizes detailed criteria, standards, and need methodologies, both general and service/facility specific, that are updated at least biennially after consultation with a technical advisory committee; and
(g) Is conducted in a transparent and accountable manner.

A detailed table illustrating the TF's worksheet is contained in Appendix C-1 (RCW 70.38.015 subsection 3).

5. Mechanisms to Monitor Ongoing Compliance

ESSHB 1688, Section 3(2) directs the TF to examine:

(f) Mechanisms to monitor ongoing compliance with the assumptions made by facilities that have received either a certificate of need or an exemption to a certificate of need, including those related to volume, the provision of charity care, and access to health services to medicaid and medicare beneficiaries as well as underinsured and uninsured members of the community.

The TF considered both statutory and rule modifications, and was guided by the Department of Health's analysis of the appropriate mechanism for each issue. The TF recommends the following modifications:

<u>Statutory Modification Recommendations – related to funding, data, and compliance</u>

- Establish a fee structure for CON applications, supplemented with other sources of revenue, to sufficiently cover the direct costs of CON review, monitoring, and other related costs.
- Create a data system for CON analysis and monitoring as a subset of a comprehensive data system for state health planning that includes improved data collection and reporting methods that reflect technological advances.
- Collect and report CON data on an ongoing basis using consistent and reliable performance measures.
- Include the following data elements for services subject to CON review:
  - Inpatient and outpatient utilization and outcomes information; and
  - Financial and utilization information related to charity care, quality, and cost regardless of the service location.
- Make data publicly available for applicants and interested observers.
- Report indications for quality and performance improvement that arise during the review process to the state health planning body and all other appropriate agencies.

- Extend the length of compliance monitoring and oversight to at least five years after project completion.
- Create and enforce penalties for non-compliance with the provisions and conditions of CON approved applications. Examples of appropriate penalties include, but are not limited to, significant fines, revocation of the CON award, moratorium on future CON applications for a specified period, and/or revocation of license.

Detailed tables showing the TF's worksheets are provided in Appendices C-3 (RCW 70.38.105 new subsection), C-5 (RCW 70.38.125 subsections 3 and new), C-6 (RCW 70.38.135 subsection 3), and C-7 (RCW 43.70.052 new subsection).

Rule Recommendations – related to communication and monitoring

- Improve and maintain communication among affected state agencies to permit crosschecking between licensing, certification, registration, and/or reimbursement sources that support compliance monitoring.
- Retain current process of periodic progress reports from project approval through completion, followed by documentation of total costs.
- Monitor the provision of the approved service:
  - Consistent with the assumptions that led to approval;
  - To the population promised;
  - At the promised level of charity care;
  - In compliance with added conditions;
  - Observing the utilization/volume standards appropriate in tertiary services (or demonstrating that departure from the assumptions is reasonable [evidence-based wherever possible] and has not negatively affected outcomes); and
  - Ensuring the "special conditions/representations" that resulted in the decision to grant the certificate were attained.
- Expand monitoring systems as data capabilities develop or permit.

Additional Recommendations – related to licensure, certification, and data

Because of the close link between the purposes of state licensure and CON review, the TF recommends that all CON reviewed items be either licensed or certified by the state of Washington, and that operational data systems be developed and linked to licensure and certification.

6. Program Processes

ESSHB 1688, Section 3(2) directs the TF to examine:

(e) The timeliness and consistency of certificate of need reviews and decisions, the sufficiency and use of resources available to the department of health to conduct timely reviews, the

means by which the department of health projects future need for services, the ability to reflect differences among communities and approaches to providing services, and clarification on the use of the concurrent review process; and

The TF considered both statutory and rule modifications, and was guided by the Department of Health's analysis of the appropriate mechanism for each issue. The TF recommends the following modifications:

Statutory Modification Recommendations – related to operational improvement and transparency

- Use expedited and/or abbreviated cycles for applications that comply with the state health plan and have minimal impact on area health services.
- Invite CON proposals based on service needs that are determined by the state health plan.
- Use evidence-based health care criteria and standards that are consistent with the state health plan and are updated at least biennially.

A detailed table showing the TF's worksheet appears in Appendix C-6
(RCW 70.38.135 subsections 3 and new).

Rule Recommendations – related to process and transparency

- Maintain the current process flow of staff screening followed by public comment, with a final decision by the Secretary of the Department of Health or her/his designee.
- Continue to obtain quality, access, utilization, and licensure data related to CON applicants.
- Retain the current methodologies for defining service areas.
- Maintain the public notification of Letters of Intent and the receipt of the applications, which may trigger submission of competing applications.
- Continue to batch competing applications for similar service types and geographic areas into concurrent review cycles.
- Assure that the burden of proof is on the applicant to provide documentation of community need and detailed responsiveness to CON criteria and standards.
- Assure the availability of sufficient resources (including staff or consultants with appropriate technical expertise to evaluate the applications).
- Provide a timely, accountable, and reasonable process in compliance with existing statutes/rules.
- Assure reliability and consistency of review by analysts.
- Through rule making, create a more efficient and transparent application process.

- Through rule making, create criteria for making tie-breaking decisions between two or more appropriate and equivalent applications.
- Use electronic applications, processing, and reporting for public transparency, accountability, and public input.
- Provide transparency during all phases of the CON process (screening by staff, post-analysis by staff, pre-public comment, and post-public comment) of data related to:
  - Volumes,
  - Application types,
  - Appeals or resolutions,
  - Denials,
  - Compliance, and
  - Other related application data and information.

The TF reviewed the Performance Audit of the CON Program from the Joint Legislative Audit and Review Committee, and used its six recommendations as a reference tool in the preparation of these recommendations (see Appendix D-1).

7. Other Issues of Concern

After much discussion, the TF concluded that the CON Program would be most effective within the context of a broader state health planning process supported by an adequate data reporting system.

State Health Plan

The CON process was originally designed within the context of a formal state health planning process. Need determinations that drove CON decisions about proposed facilities and services emanated from the state health plan. The Washington State Health Plan, however, has not been updated since 1987. Thus, the current CON Program operates in a planning vacuum, with no formal state health plan to guide its need determinations and decisions. The TF repeatedly observed that the lack of a state health plan compromised the CON Program's ability to achieve its goals – or even to articulate what its goals should be.

The TF recommends that the state reenergize its formal health planning process, create a new and current state health plan, and update it biennially. Based on a review of health plans in several other states, the TF recommends that the following seven components be included in Washington's state health plan:

- **Rationale** including vision, purpose, mission, and principles;
- **Participants** including state agencies, providers, purchasers, consumers, and advocates;
- **Existing systems** including health status, inventory facilities/equipment/services, and data;
- **Proposed description** of health system at a given planning horizon;

- **Action plan for implementation** including goals, objectives, criteria, standards, priorities, and strategies;

- **Evaluation** including monitoring, data reporting, feedback, and updating; and

- **Appendices** including planning areas, acronyms, references, and others.

Appendix B-4 provides samples of the tables of contents from several state health plans, including Washington's 1987 plan. A synthesis of samples has also been provided to capture some of the important features of each.

With this perspective, the TF recommends the following additional revisions to the purpose and goals of the CON Program (RCW 70.38.015) outlined on pages 8 and 9:

(*That a strategic health planning process, responsive to changing health and social needs and conditions, is essential to the health safety, and welfare of the people of the state. Such a process shall be reviewed and updated biennially by a designated state agency or body;)*

- To recognize the close interrelationship of health planning concerns and emphasize health care expenditure control, including cost-effectiveness and cost-benefit analysis;

- To integrate criteria for evidence-based medicine;

- To invite proposals for CON in response to service needs determined by the state health plan; and

- To use expedited and/or abbreviated cycles for applications that comply with the state health plan and have minimal impact on area health services.

A detailed table of these recommendations appears in Appendix C-1
(RCW 70.38.015 subsections 1 and 3).

Washington State Certificate of Need Program
Task Force Report

Appendices

Background

Appendix A-1
Task Force Composition and Meetings

Member Name	Representing	Meetings F: face-to-face T: telephone conference call													
		F: 10/06/05	T: 10/19/05	T: 11/09/05	F: 11/30/05	F: 01/03/06	T: 01/25/06	T: 02/08/06	T: 03/06/06	F: 03/29/06	F: 05/17/06	T: 06/14/06	F: 06/28/06	F: 08/16/06	F: 10/11/06
Rep. Barbara Bailey (R)	Legislator Representative, Member, House Health Care Committee	X	X	X	X	X			…meeting canceled…	X		X	X	X	X
Norman Charney, MD	Private Employer-Sponsored Health Benefits Purchaser Representative	X	X	X	X	X	X	X		X	X		X		X
Rep. Eileen Cody (D)	Legislator Representative, Chair, House Health Care Committee	X			X	X				X	X		X	X	X
Sen. Alex Deccio (R)	Legislator Representative, Ranking Republican, Senate Health & Long Term Care Committee		X				X	X							
Dorothy Graham	Private Employer-Sponsored Health Benefits Purchaser Representative		X	X	X	X	X	X		X		X	X	X	X
Steve Hill	Administrator, Health Care Authority	X	X	X	X	X	X	X		X	X		X	X	X
Denise Hopkins, DDS	Health Care Consumer Representative	X		X	X	X	X	X		X	X			X	X
Kathy Marshall	Division Director, Aging and Disability Services Administration, Department of Social and Health Services	X	X	X	X	X	X			X	X	X	X	X	X
Palmer Pollock	Health Care Provider Representative				X	X	X	X		X	X		X	X	X
Mary Selecky	Secretary, Department of Health		X	X	X	X	X	X		X	X	X	X	X	X
Jon Smiley	Health Care Provider Representative				X	X		X		X	X	X		X	
Robby Stern	Labor Representative, (Taft-Hartley Plans)	X	X	X	X	X	X			X	X		X	X	X
Sen. Pat Thibaudeau (D)*	Legislator Representative, Vice Chair, Senate, Health & Long Term Care Committee	X		X	X										
Janet Varon	Health Care Consumer Representative	X	X	X	X	X	X			X	X		X		X
Carolyn Watts, PhD Task Force (TF) Chair	Health Care Economist Representative	X	X		X	X	X	X		X	X	X	X	X	X
Rick Woods	Health Carrier Representative	X	X	X	X	X	X				X	X	X	X	X

**resigned from Task Force because of conflicting schedule*

Appendix A-2
Technical Advisory Committee Composition and Meetings

Member Name	Representing	Meetings F: face-to-face T: telephone conference call						
		F: 11/17/05	F: 12/13/05	F: 02/16/06	F: 03/16/06	F: 04/13/06	F: 05/25/06	F: 06/08/06
Jody Carona	Consultant, Health Facilities Planning and Development	X	X	X	X		X	X
Scott Norris Faringer	Administrator, Yakima Ambulatory Surgical Center	X	X					
Donna Goodwin	Vice President of Operations, Family Home Care	X	X	X	X	X	X	X
William Hagens	Clinical Professor, University of Washington School of Public Health and Community Medicine, Member, State Nursing Care Quality Assurance Commission	X	X	X			X	X
Eleanor Hamburger	Attorney, Siranni, Youtz, Meier and Spoonemore	X	X	X		X	X	X
Debra Hatfield*	Consumer, King County American Heart Association	X						
Michael Kelly, MD*	Nephrologist, Minor & James Clinic		X					
Jean Pfeifer, RN, BSN	Staff Nurse/NICU, Children's Hospital	X	X	X	X	X	X	
Palmer Pollock TF Representative	Planning Administrator, Northwest Kidney Centers	X	X	X	X		X	X
Gil Rodriguez, MD	Anesthesiologist, Chief Medical Officer/VP Marketing and Planning, Southwest Washington Medical Center	X		X	X		X	
Simeon Rubenstein, MD	Cardiologist, Group Health Cooperative, Clinical Professor /Cardiology, University of Washington School of Medicine	X	X		X	X		
Scott Scherer*	Vice President and General Manager, Aircraft Financial Services, Boeing							
Sue Sharpe	Health Planning Consultant	X	X		X		X	X
Jon Smiley TF Representative	CEO, Sunnyside Community Hospital	X	X	X		X		X
Lloyd Lee Smith*	Chief Operating Officer, Spokane County Health District							

**resigned from Technical Advisory Committee because of conflicting schedules*

Appendix A-3
ESSHB 1688 Issues to Be Addressed

(Editor's Note: indenting applied to improve readability, original has even left margin)

Section 3(2) The task force shall, at a minimum, examine and develop recommendations related to the following issues:

(a) The need for a new and regularly updated set of service and facility specific policies that guide certificate of need decisions;
(b) A review of the purpose and goals of the current certificate of need program, including the relationship between the supply of health services and health care outcomes and expenditures in Washington state;
(c) The scope of facilities, services, and capital expenditures that shall be subject to certificate of need review, including consideration of the following:
  (i) Acquisitions of major medical equipment, meaning a single unit of medical equipment or a single system of components with related functions used to provide medical and other health services;
  (ii) Major capital expenditures. Capital expenditures for information technology needed to support electronic health records shall be encouraged;
  (iii) The offering or development of any new health services, as defined in RCW 70.38.025, that meets any of the following:
    (A) The obligation of substantial capital expenditures by or on behalf of a health care facility that is associated with the addition of a health service that was not offered on a regular basis by or on behalf of the health care facility within the twelve-month period prior to the time the services would be offered;
    (B) The addition of equipment or services, by transfer of ownership, acquisition by lease, donation, transfer, or acquisition of control, through management agreement or otherwise, that was not offered on a regular basis by or on behalf of the health care facility or the private office of a licensed health care provider regulated under Title 18 RCW or chapter 70.127 RCW within the twelve-month period prior to the time the services would be offered and that for the third fiscal year of operation, including a partial first year following acquisition of that equipment or service, is projected to entail substantial incremental operating costs or annual gross revenue directly attributable to that health service;
  (iv) The scope of health care facilities subject to certificate of need requirements, to include consideration of hospitals, including specialty hospitals, psychiatric hospitals, nursing facilities, kidney disease treatment centers including freestanding hemodialysis facilities, rehabilitation facilities, ambulatory surgical facilities, freestanding emergency rooms or urgent care facilities, home health agencies, hospice agencies and hospice care centers, freestanding radiological service centers, freestanding cardiac catheterization centers, or cancer treatment centers. "Health care facility" includes the office of a private health care practitioner in which surgical procedures are performed;
(d) The criteria for review of certificate of need applications, as currently defined in RCW 70.38.115, with the goal of having criteria that are consistent, clear, technically sound, and

reflect state law, including consideration of:

(i) Public need for the proposed services as demonstrated by certain factors, including, but not limited to:
  (A) Whether, and the extent to which, the project will substantially address specific health problems as measured by health needs in the area to be served by the project;
  (B) Whether the project will have a positive impact on the health status indicators of the population to be served;
  (C) Whether there is a substantial risk that the project would result in inappropriate increases in service utilization or the cost of health services;
  (D) Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
  (E) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project, including whether there is data to indicate that the proposed health services would constitute innovations in high quality health care delivery;

(ii) Impact of the proposed services on the orderly and economic development of health facilities and health resources for the state as demonstrated by:
  (A) The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
  (B) The impact of the project on the ability of existing affected providers and facilities to continue to serve uninsured or underinsured residents of the community and meet demands for emergency care;
  (C) The availability of state funds to cover any increase in state costs associated with utilization of the project's services; and
  (D) The likelihood that more effective, more accessible, or less costly alternative technologies or methods of service delivery may become available;

(e) The timeliness and consistency of certificate of need reviews and decisions, the sufficiency and use of resources available to the department of health to conduct timely reviews, the means by which the department of health projects future need for services, the ability to reflect differences among communities and approaches to providing services, and clarification on the use of the concurrent review process; and

(f) Mechanisms to monitor ongoing compliance with the assumptions made by facilities that have received either a certificate of need or an exemption to a certificate of need, including those related to volume, the provision of charity care, and access to health services to medicaid and medicare beneficiaries as well as underinsured and uninsured members of the community.

Appendix A-4
State of Washington Orientation Materials

Copies of these materials are available through June 30, 2007, on the Health Care Authority website at http://www.hca.wa.gov/contf/index.shtml

• **Washington CON History:**
Department of Health (DOH) representatives Gary Bennett, Bart Eggan, Byron Plan and Janis Sigman provided a detailed presentation of significant events from the 1971 initiation of the state of Washington CON Program through 2004, as well as described the licensure process and non-hospital surgical setting issues. Supporting presentation materials prepared by DOH included:

- CON History: a six-slide PowerPoint presentation covering an annotated period of Washington CON milestones from 1971-2004
- Health Planning: a one-page description of the 1971 CON authorization and initial health planning, including the State Health Coordinating Council and Health Systems Agencies
- CON Basic: a three-page overview of the Washington CON Program, what it reviews, its general review criteria, statutes, and rules, plus contact information
- CON Coverage Comparison Pre-1989 – Today: a three-page table comparing the services and facilities reviewed before and after 1989, a point of significant regulatory reduction
- CON Concurrent Review Cycles: a two-page table comparing the review cycles, letter of intent due dates, and other deadline information about each service and facility grouping
- CON Timeline: a two-page table illustrating the timelines for CON applications undergoing CON review including regular, expedited, and concurrent reviews
- 10-year Decision Charts: a 12-page set of graphic representations of the number of CON applications approved and denied presented by type of service or facility
- A Statewide Assessment of Health Status, Health Risks, and Health Care Services: a link to the 129-page 2004 Supplement of "The Health of Washington State"
- Washington State Health Report: a link to the annual 2004 Washington State Health Report

Joyce Stockwell from the Department of Social and Health Services also described long-term care, licensure, and monitoring activities during the same period.

• **Certificate of Need Study - Phase I:**
Mercer Human Resource Consulting submitted a report on August 18, 2005, that summarized the purpose of CON, outlined the findings of the CON assessments since 1999 — specifically, the impacts of cost, access, quality, and technology — and provided conclusions and suggestions for Phase II of the Washington CON project. The processes employed by other states in implementing their CON requirements and procedures were also reported in this paper's appendices.

• **State of Washington Joint Legislative Audit and Review Committee (JLARC):**
Report 99-1 *Effects of Certificate of Need and Its Possible Repeal* was prepared by the Health Policy Program of the University of Washington's School of Public Health and Community Medicine for JLARC and released on January 8, 1999. The study found that CON had not controlled overall health care spending or hospital costs. The study further found conflicting or limited evidence about: the effects of CON on the quality and availability of other health care services, and the effects of repealing CON. Three policy options were presented for consideration:

(1) Reform CON to address its current weaknesses;
(2) Repeal parts or all of the program while taking steps to increase monitoring and ensure that relevant goals are being met; and
(3) Conduct another study to identify more clearly the possible effects of repeal in Washington State.

JLARC was mandated by ESSHB 1688 to conduct a performance audit of the Department of Health's administration and implementation of its CON Program. The study objectives included the following questions:

- How does DOH evaluate CON applications (are decisions consistent with statute, and what data and analysis does DOH use)?
- Are decisions consistent with each other?
- How does DOH measure the performance of the CON Program?
- How does DOH monitor CON projects?

• **State Health Plan:**
The last *Washington State Health Plan* is an 853-page document produced December 30, 1980. A 378-page *Part II* was released in 1982. Two addendums were added in 1987: *Volume 1: Health Principles, Goals, and Strategies* (54 pages) and *Volume 2: Performance Standards for Health Facilities and Services* (122 pages). No updates to this Plan have been released since May 12, 1987.

• **Governor Christine O. Gregoire:**
Steve Hill, as the delegate of Governor Gregoire, articulated the Governor's state health care priorities in presenting the following Five-point Strategy for Improving Health Care in her Policy Brief called "Raising the Bar for Health Care":

- Emphasize evidence-based health care
- Promote prevention, healthy lifestyles and healthy choices
- Better manage chronic care
- Create more transparency in the health care system
- Make better use of information technology

• **Washington Purchasers Perspectives:**
Laura Boyd, President, Health Care Purchasers Association, presented an overview of how business views health care financing, the impact of health care costs, collaborative efforts, the expectations of government's role in health care, and recommendations for a dynamic health care plan for health care delivery.

Appendix A-5
National Experience Orientation Materials

Copies of these are available through June 30, 2007, on the HCA website at
http://www.hca.wa.gov/contf/index.shtml

• **CON National Experience:**
Thomas R. Piper of MacQuest Consulting provided numerous descriptions of the 37 diverse CON programs in the United States, including:

- National CON Perspective and Experience: "Key State" Comparisons
- Selected Review of State Public Oversight Efforts
- 2006 Relative Scope and Review Thresholds: CON Regulated Services by State
- Elements of Effective Regulation
- State Responses About CON Monitoring and Data
- National Directory of Health Planning, Policy, and Regulatory Agencies 2005
- National Health Data Review
- State Health Plan Outlines

• **CON Health Care Policy Programs:**
- A review of Certificate of Need Health Care Policy Programs: At the Intersection of Science and Politics: a 31-slide PowerPoint by Bruce Spector, Esq., from Vermont
- The Precarious Pricing System For Hospital Services: a link to the research article by Christopher P. Tompkins, Stuart H. Altman, and Efrat Eilat, *Health Affairs*, Vol. 25, No. 1, January/February 2006, p.45, (DOI 10.1377/hlthaff.25.1.45)
- Failure of Government Central Planning: Washington's Medical Certificate of Need Program: a link to a large multi-page January 2006 article by John Barnes, Policy Analyst at the *Washington Policy Center*

• **Vermont Experiences:**
Bruce Spector, Esq., from the state of Vermont provided significant CON perspectives based on his Vermont experience, including:

- Health Resource Allocation Plan
- Vermont CON Reform Law
- Vermont HRAP: Section Four, CON Standards

• **Michigan and Business Experiences**:
Renee Turner-Bailey, MHSA, presented a series of CON perspectives based on her CON Commission and automakers experience in Michigan, as well as her involvement in the National Quality Forum, Leapfrog, and other participation, including:

- Overview of Compliance Monitoring Options and Opportunities
- Health Care Quality Efforts in the U.S. – An Employer's Perspective

• **Maine Dirigo Health Experiences**:
Cynthia A. Smith, RN, JD, and Kevin Russell, FSA, MAAA, of Mercer Consulting presented observations about the Certificate of Need/Capital Investment Fund and Savings Calculations that they are working with in Maine.

• **Specialty Hospitals:**
- Do Specialty Hospitals Promote Price Competition?: a link to the small multi-page Issue Brief No. 103 from the *Center for Studying Health System Change* by Robert A. Berenson, Gloria J. Bazzolit, and Melanie Au, January 2006

• **FTC/DOJ Study:**
The Federal Trade Commission and the Antitrust Division of the Department of Justice based this report on 27 days of joint hearings from February through October 2003; a Commission sponsored workshop in September 2002; and independent research. The hearings broadly examined the state of the health care marketplace and the role of competition, antitrust, and consumer protection in satisfying the preferences of Americans for high-quality, cost-effective health care. A small portion of the study criticized CON as shown in the links on the HCA website for documents and responses:

- *July 2004 Improving Health Care: A Dose of Competition*
  Federal Trade Commission and Department of Justice
- *The Federal Trade Commission & Certificate of Need Regulation: An AHPA Critique*
- *Improving Health Care: A Dose of Competition:*
  AHPA Response Arguments in Favor of Planning and CON Regulation
- *A Dose of Competition: AHPA Response:*
  Arguments Against FTC Assertions and Assumptions

• **Other State Statutes, Rules, and Plans:**
Descriptive information was gathered about key states both with and without CON programs to describe purposes, processes, and experiences with efforts to address health care cost, access, and quality (see HCA website for Internet links):

- Kentucky:
  Kentucky CON,
  Statutes, and
  Regulations;
- Maine:
  Procedures Manual, and
  Statutes;
- Michigan:
  CON Site,
  Statute,
  Rules,
  CON Review Standards,
  Michigan CON Program Performance Audit, and
  Follow-Up Report;
- Minnesota:
  Press Release: Governor Pawlenty Unveils "SMART BUY" Alliance,
  Minnesota's Smart Buy Alliance: A Coalition of Public/Private Purchasers Demands Quality and Efficiency in Health Care,
  Minnesota Health Information: A Guide to Health Care Quality and Cost in

Minnesota, and
Governor's Health Cabinet;
- Missouri:
Rulebook, which includes Rules, Statutes, and Process;
- New York:
Capacity Matters - Finger Lakes Health Systems Agency, and
Capacity and Use of High Tech Medical Services in Upstate New York;
- North Carolina:
Statutes,
Rules,
2006 State Medical Facilities Plan,
Overview of CON Process, and
Summary of Facilities and Activities Requiring CON;
- Ohio:
Certificate of Need,
Rules, and
Chapter 3702: Hospital Care Assurance Program;
- Oregon:
Certificate of Need,
Statutes, and
Oregon Administrative Rules: Purpose, Applicability, and Definitions for CON; and
- Vermont:
Certificate of Need,
Regulations, and
Statutes.

Appendix A-6
Washington Expert Speakers Providing Professional Input

Joint Legislative Audit and Review Committee
Ruta Fanning, Legislative Auditor
Cynthia L. Forland, Research Analyst
Lisa Jeremiah, Research Analyst
Keenan Konopaski, Audit Coordinator

Department of Health
Gary Bennett, Director,
Facilities and Services Licensing, Health Services Quality Assessment
Bart Eggan, Executive Manager,
Office of Certification and Technical Support, Health Services Quality Assessment
Brian Peyton, Director, Policy, Legislative and Constituent Relations
Byron Plan, Executive Manager, Office of Health Care Survey
Janis R. Sigman, Manager, Certificate of Need Program
Jeanette Zaichkin, RNC, MN, Public Health Nurse Consultant, Maternal and Child Health

Department of Social and Health Services
Irene Owens, Office Chief,
Policy, Program Development & Training Unit, Residential Care Services, ADSA
Joyce Pashley Stockwell, Director, Residential Care Services

Mercer Government Human Services Consulting
Cynthia A. Smith, RN, JD, Principal
Kevin Russell, FSA, MAAA, Associate

Health Care Authority
Nancy Fisher, MD, MPH, Medical Director
Linda M. Glaeser, Director of Quality for Contracted Clinical Programs

Other
Laura Boyd, President, Health Care Purchasers Associations
Phil Lund, MD, Past President, Washington State Radiology Society
Marcia Rohlik, RN, MN, Mason General Hospital

Work Group Resources

Appendix B-1

Technical Advisory Committee Worksheet of Health Services and Situations Eligible for Certificate of Need Review

(**bold underlined** reviewed in Washington, ***bold italics*** referenced in statute, notes: [1]Expansion, [2]NO review of service, [3]Statutory Guiding Principles)

New	Expsn[1]	NOrv[2]	Type of Service	Guiding Principles[3]
			Acute Inpatient	
☒	☒	☐	***Medical-surgical licensed beds***	specific needs of area, accessibility, impact of new health facilities on expenditures
☒	☒	☐	***Rehabilitation (Level I)***	specific needs of area, accessibility, impact of new health facilities on expenditures
☒	☒	☐	***Psychiatric (licensed)***	accessibility, effect on facilities for uninsured/underinsured
☒	☒	☐	***Obstetrics (Levels II & III)***	positive impact on quality outcomes
☒	☒	☐	***Pediatrics (specialty)***	positive impact on quality outcomes, effect on underinsured/uninsured
☐	☐	☒	***Substance abuse (adult)***	
☐	☐	☒	***Substance abuse (child/adolescent)***	
☐	☐	☒	***Intensive care unit (ICU)/critical care unit***	
☒	☒	☐	***Neonatal ICU (Levels II & III)***	data to indicate high-quality health care, positive impact on quality outcomes
☐	☐	☒	***Adult ICU***	
☒	☒	☐	***Pediatric ICU***	positive impact on quality outcomes, effect on underinsured/uninsured
☒	☒	☐	***Burn units (specialty)***	specific health needs of area
☒	☒	☐	***Specialty hospitals (heart, orthopedic, surgical)***	substantial risk for inappropriate use, effect on underinsured/uninsured, total health cost
			Long Term Care	
☒	☒	☐	Subacute care **(Medicare distinct part)**	acessibility, specific health needs of the area
☐	☐	☒	Boarding homes (assisted living facilities)	
☐	☐	☒	Specialty care assisted living facility	
☐	☐	☒	Intermediate care mentally retarded facility	
☒	☒	☐	***Long term care hospital***	specfic health needs of area, positive impact on quality outcomes, state funds to cover cost
☒	☒	☐	***Nursing homes***	specific needs of area, positive impact on quality outcomes, state funds to cover cost
☐	☐	☒	Swing beds **(>5 beds)**	
☐	☐	☒	Residential care facility	
☐	☐	☒	Psychiatric residential treatment facility	
☒	☒	☐	Continuing care retirement center **(5-yr Medicaid life care requirement)**	specific needs of area
☐	☐	☒	Adult family homes	
			Medical Equipment	
☒	☒	☐	***Cyber knives***	total health expenditures, specific health needs of area, positive impact on quality outcomes
☒	☒	☐	***Computed tomography (CT) scanners***	substantial risk for inappropriate utilization, accessibility
☒	☒	☐	***Gamma knives***	total health expenditures, specific needs of area, positive impact on quality outcomes
☐	☐	☒	Hyperbaric chambers	
☒	☒	☐	***Magnetic resonance image scanners***	substantial risk for inappropriate utilization
☒	☒	☐	***Positron emission tomography (PET) scanners***	substantial risk for inappropriate utilization
☒	☒	☐	***Positron emission tomography /computed tomography scanners***	substantial risk for inappropriate utilization (cumlative radiation,etc)
☒	☒	☐	***Linear accelerators***	specific needs of area, state funds to cover increased cost
☒	☒	☐	***Robotic surgery***	specific needs of area, state funds to cover increased cost
☐	☐	☒	Ultrasound	
☐	☐	☒	Heart-lung bypass machines	

Outpatient Services

☒	☒	☐	***Freestanding emergency departments***	effect on underinsured/uninsured, accessibility
☒	☒	☐	***Freestanding radiological service centers***	substantial risk for inappropriate utilization, specific needs of area
☐	☐	☒	Behavioral health services	
☐	☐	☒	Opiate replacement treatment facilities (methadone)	
☐	☐	☒	***Urgent care facilities***	
☒	☒	☐	***Diagnostic imaging centers***	substantial risk for inappropriate utilization, specific needs of area
☒	☒	☐	***Oncology (cancer) treatment centers***	substantial risk for inappropriate utilization, specific needs of area
☐	☐	☒	***Substance abuse services***	
☐	☐	☒	Community clinic	

Procedures

☒	☒	☐	***Diagnostic cardiac catheterization***	positive impact on quality outcomes, substantial risk for inappropriate utilization
☒	☒	☐	***Therapeutic cardiac catheterization***	positive impact on quality outcomes, substantial risk for inappropriate utilization
☒	☒	☐	***Elective angioplasty***	positive impact on quality outcomes, substantial risk for inappropriate utilization
☐	☐	☒	***Primary/emergent angioplasty***	
☐	☐	☒	***Lithotripsy***	
☒	☒	☐	***Kidney treatment centers (including hemodialysis)***	substantial risk for inappropriate utilization, positive impact on quality outcomes

Surgery

☒	☒	☐	***Cardiac surgery suites***	substantial risk for inappropriate utilization, positive impact on qualtiy outcomes
☐	☐	☒	***General inpatient surgery suites***	
☒	☒	☐	***Outpatient (any freestanding ambulatory)***	substantial risk for inappropriate utilization, effect on underinsured/uninsured
☐	☐	☒	***Outpatient (hospital)***	
☒	☒	☐	***Open heart (adult)***	accessibility, positive impact on outcomes, data/QI, total health expenditures
☒	☒	☐	***Open heart (pediatric)***	accessibility, positive impact on outcomes, data/QI, total health expenditures
☒	☒	☐	***Solid organ transplant (adult)***	accessibility, positive impact on outcomes, data/QI, total health expenditures
☒	☒	☐	***Solid organ transplant (pediatric)***	accessibility, total health expenditures, data/quality indicators
☒	☒	☐	***Bone marrow/stem cell transplants***	accessibility, total health expenditures, data/quality indicators
☒	☒	☐	**Single-specialty freestanding ambulatory surgery centers**	substantial risk for inappropriate utilization, effect on underinsured/uninsured, total cost
☒	☒	☐	***Physician practice office-based surgery***	substantial risk for inappropriate utilization, positive impact on quality outcomes
☒	☒	☐	Hospital-based ambulatory surgery center	substantial risk for inappropriate utilization, positive impact on quality outcomes

Other Services

☒	☒	☐	***Home health care (Medicare/Medicaid eligible)***	data for QI, substantial risk for inappropriate utilization, specific needs of area
☒	☒	☐	***Hospice care centers (inpatient)***	specific needs of area
☒	☒	☐	***Hospice agencies (outpatient, Medicare/Medicaid)***	specific needs of area, state funds to cover increased cost
☐	☐	☒	Air ambulance	
☐	☐	☒	***Information technology***	
☒	☒	☐	Emerging technology and new service categories	total health expenditure, state funds to cover increased cost, substantial risk for inapprop. use
☐	☐	☒	Birthing centers	
☒	☒	☐	Research and demonstration projects	impact of new health services on quality

Appendix B-1 (continued)
Technical Advisory Committee Worksheet of Health Services and Situations Eligible for Certificate of Need Review

Statutory Guiding Principles

(a version of ESSHB 1688, sections 3(1) and 3(2)(d) abbreviated by the Technical Advisory Committee to more concisely guide their efforts):

The Task Force is to be guided by considering the following principles:

1. Impact of the supply of health services on utilization.
2. Effect of new health services/facilities on expenditures.
3. Impact of new health facilities/services/equipment on quality and outcomes.
4. Current coverage of facilities and services is to remain.

The Task Force is to develop criteria, including consideration of:

1. Public Need:
   (a) Specific health needs of an area
   (b) Positive impact on health indicators of population served
   (c) Substantial risk for inappropriate utilization
   (d) Accessibility for all residents
   (e) Data to indicate quality indicators
2. Impact on orderly economic development of health facilities and health resources:
   (a) Impact on total health expenditures
   (b) Effect on existing providers and facilities' services for underinsured/uninsured
   (c) Availability of state funds to cover increased cost
   (d) Potential of more effective or accessible or less costly alternatives

Appendix B-2

Task Force Worksheet of Health Facilities, Equipment, and Services Eligible for Certificate of Need Review Summary

(**bold underlined** currently reviewed in Washington, ***bold italics*** - referenced in ESSHB 1688)

Proposed for No Review

Long Term Care
Boarding homes (assisted living facilities)
Specialty care assisted living facilities
Intermediate care
mentally retarded facilities
Residential care facilities
Psychiatric residential treatment facilities
Adult family homes

Medical Equipment
Hyperbaric chambers
Ultrasound machines
Heart-lung bypass machines
Computed tomography (CT) scanners

Outpatient Services
Behavioral health services
Opiate replacement treatment
facilities (methadone)
Urgent care facilities
Substance abuse services
Community clinics

Procedures
Primary/emergent angioplasty
Lithotripsy

Other Services
Information technology
(needed to support electronic
health records)
Medical office buildings
Birthing centers

Proposed for Continued Review

Acute Inpatient
Substance abuse (adult)*
Substance abuse (child/adolescent)*
Intensive care unit (ICU)/
critical care unit*
Adult ICU*
Medical-surgical licensed beds
Rehabilitation (Level I)
Psychiatric beds (licensed)
Obstetrics (Levels II & III)
Pediatrics (specialty) includes ICU
Neonatal ICU (Levels II & III)
Burn units (specialty)
Specialty hospitals
(heart, orthopedic, surgical)

Long Term Care
Subacute care **(Medicare distinct part)**
Long term care hospitals
Nursing homes
Swing beds **(>5 beds)**
Continuing care retirement centers
(5-year Medicaid life care requirement**)**

Procedures
Therapeutic cardiac catheterization
Elective angioplasty
Kidney treatment centers (including hemodialysis)

Surgery
General inpatient*
Outpatient (hospital)*
Hospital-based ambulatory surgery centers*
Open heart (adult, pediatric)
Solid organ transplant (adult, pediatric)
Bone marrow*/stem cell* ***transplants***
Freestanding ambulatory surgery centers
open to non-owner practitioners

Other Services
Home health agencies (Medicare/Medicaid)
Hospice care centers (facilities)
Hospice agencies (Medicare/Medicaid)

Proposed for New Review

Medical Equipment
Cyber knives
Gamma knives
Positron emission tomography scanners
Positron emission tomography/
computed tomography scanners
Linear accelerators
Robotic surgery

Outpatient Services
Freestanding emergency departments
Freestanding radiological service centers
Diagnostic imaging centers
Oncology (cancer) treatment centers

Surgery
Cardiac surgery (outpatient and
not done under a hospital license)
All ambulatory surgery centers
regardless of owner or operator

Proposed for Future Study

Acute Inpatient
Conversion of acute care bed type

Long Term Care
Conversion of long-term care bed type

Medical Equipment
Magnetic resonance image scanners

Procedures
Diagnostic cardiac catheterization

Surgery
Physician practice office-based surgery

Other Services
Research and demonstration projects
Air ambulances
Home health agencies
(regardless of payment source)
Hospice agencies
(regardless of payment source)

Financial Thresholds

***These are part of hospital review**

Appendix B-3
New Health Care Items Recommended for CON Review by Task Force

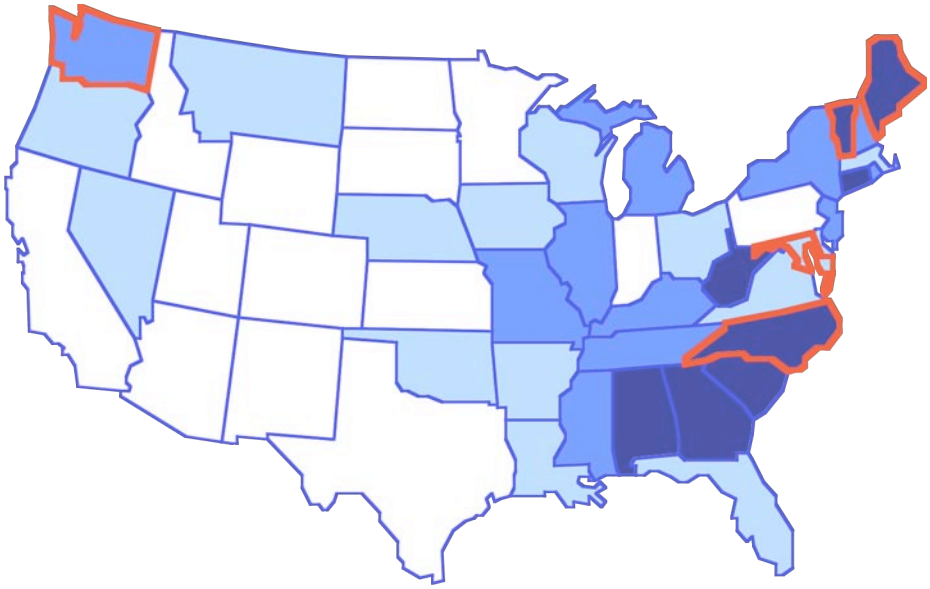
ITEM DESCRIPTION	STATES WITH CON REVIEW	REF*	RATIONALE
Medical equipment			
Cyber knives	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, MO, HI, MI, NH, AL, IA, IL, VA, MD, DE, MA	2, 4, 5	Avg. cost: $7,000,000, very new variation on linear accelerator, significant potential for overuse
Gamma knives	CT, VT, AK, GA, WV, ME, NC, MS, SC, DC, NY, RI, MO, HI, MI, AL, IL, VA, MA	1, 4, 5	Avg. cost: $4,000,000, old technology, major revenue source for providers, limited use
Positron emission tomography scanners	CT, VT, AK, GA, WV, ME, NC, MS, SC, TN, DC, NY, RI, MO, HI, MI, NH, AL, VA, MA, IA, IL, DE	2, 5	Avg. cost: $2,200,000, fast growing, major revenue source for providers, significant potential for misuse
Positron emission tomography/ computed tomography scanners	CT, VT, AK, GA, WV, ME, NC, MS, SC, TN, DC, NY, RI, MO, HI, MI, NH, AL, VA, MA, IA, IL, DE	2, 5	Avg. cost: $3,000,000, fast growing, major revenue source for providers, significant potential for misuse
Linear accelerators	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, MO, HI, MI, NH, AL, IA, IL, VA, MD, DE, MA	2, 4, 5	Avg. cost: $2,500,000, fast growing, major revenue source for providers, significant potential for misuse
Robotic surgery	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, WA, IA, IL, VA, MT, MD, DE, MA, NV	2, 4, 5	Avg. cost: $1,000,000, very new technology, moderate growth, potential uses still under development
Outpatient services			
Freestanding emergency departments	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, IA, IL, VA, MT, MD, DE, MA, NV	2, 3, 5	Min. cost: $3,000,000, growing outpatient trend, major revenue source, very high potential for misuse
Diagnostic imaging centers	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, IA, IL, VA, MT, MD, DE, MA, NV	2, 3, 5	Min. cost: $3,000,000, growing outpatient trend, major revenue source, very high potential for misuse
Freestanding radiological service centers	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, MO, HI, MI, NH, AL, IA, IL, VA, MD, DE, MA	1, 4, 5	Min. cost: $4,000,000, fast growing, major revenue source, outpatient growth is booming, quality is concern
Oncology (cancer) treatment centers	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, MO, HI, MI, NH, AL, IA, IL, VA, MD, DE, MA	1, 4, 5	Min. cost: $4,000,000, fast growing, major revenue source, outpatient growth is booming, quality is concern
Surgery			
Ambulatory surgery centers (regardless of owner or operator)	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, WA, IA, IL, VA, MT, MD, DE, MA, NV	2, 3, 5	Min. cost: $1,000,000, huge outpatient trend, major revenue source, often duplicates inpatient capacity
Cardiac surgery	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, WA, IA, IL, VA, MT, MD, DE, MA, NV	1, 5	Min. cost: $1,000,000, huge outpatient trend, major revenue source, often duplicates inpatient capacity

***Task Force Recommended Criteria for CON Review and Regulation of Additional Health Services**

Any health care facility, major medical equipment or health service will be subject to review if one or more of the following conditions exist:

1. Tertiary services whose clinical quality and/or cost effectiveness is directly and demonstrably tied to volume, including high-risk tertiary services that require complex multi-specialty interactions.
2. New, additional or changed services that may have a significant adverse impact on the existing health delivery systems' infrastructure ability to continue to provide essential services to all residents in an economically feasible manner, or cause substantial imbalance of resident access to such services.
3. New or existing health care facility, health service, or major medical equipment for which there is inequitable state regulatory oversight.
4. Emerging or existing devices, technology and services for which clinical efficacy and patient safety have not been fully established.
5. Emerging or existing devices, technology and services for costly procedures whose appropriate utilization has not been established, and for which there is a risk of inappropriate utilization.

Appendix B-4
Other Issues Worksheet



Comparison of Selected State Health Plans

The following is a sampling of state health plans prepared for comparison and evaluation. The actual table of contents from each has been captured and displayed to fit for each example.

The state samples include: Maine, Maryland, North Carolina, Vermont, and Washington. A synthesis of samples has also been provided to capture some of the important features of each. The publication dates vary from as old as 1987 to as recent as 2006.

When comparing these samples, there are common components including:

- RATIONALE: vision, purpose, mission, and principles;
- PARTICIPANTS: state agencies, providers, purchasers, consumers, and advocates;
- EXISTING SYSTEMS: health status, inventory facilities/equipment/services, and data;
- PROPOSED DESCRIPTION: health system at a given planning horizon;
- ACTION PLAN FOR IMPLEMENTATION: goals, objectives, criteria, standards, priorities, and strategies;
- EVALUATION: monitoring, data reporting, feedback, and updating; and
- APPENDICES: planning areas, acronyms, references, and others.

This information is intended to provide an array of options from which to choose a potential "model" outline for a state health plan. CON is seen as a valuable component and implementation tool within that plan.

State Health Plan: Maine

The State Health Plan for Facilities and Services: Maryland

TABLE OF CONTENTS*

*NOTE: this general format is used as the table of contents for each of the services reviewed including cardiac surgery and percutaneous coronary intervention services (shown here), psychiatric services, emergency medical services, nursing homes, acute inpatient rehabilitation services, acute inpatient services, ambulatory surgery services, acute hospital inpatient obstetric services, alcoholism and drug abuse intermediate care facility treatment services, organ transplant services, and neonatal intensive care services.

State Medical Facilities Plan: North Carolina

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Health Resource Allocation Plan: Vermont

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State Health Plan Contents: Washington (1987)

VOLUME I: HEALTH PRINCIPLES, GOALS AND STRATEGIES

A. INTRODUCTION
B. HEALTH SYSTEM PRINCIPLES TO GUIDE STATE HEALTH POLICY/PLANNING
C. THE HEALTH OF STATE RESIDENTS
D. HEALTH GOALS AND OBJECTIVES

VOLUME II: PERFORMANCE STANDARDS FOR HEALTH FACILITIES AND SERVICES

A. INTRODUCTION
B. HEALTH FACILITY/SERVICE PERFORMANCE STANDARDS
  1. Application of Performance Standards
  2. General Performance Standards for Health Faci1ities and Services
  3. Acute Care Service Performance Standards
    a. Genera1
    b. Obstetric and Neonatal Services
    c. Pediatric Services
    d. Cancer Management Services
    e. Critical Care Services
    f. Cardiovascular Disease Services
    g. End-Stage Renal Disease Services
    h. Facility Based Adult Rehabilitation Medicine Services
    i. Computed Tomography Services
    j. Magnetic Resonance
    k. Innovative Techno1ogies
    l. Ambulatory Surgery
    m. Short Stay Psychiatric Services
  4. Long Term Care Service Performance Standards
    a. Nursing Home Services
    b. Swing Bed Services
    c. Continuing Care Retirement Communities
    d. Home Hea1th Services
    e. Hospice Services
C. FORECASTING METHODS
  1. Introduction
  2. Operating Room Need Method
    a. Summary
    b. Detailed Method
      (1) Assumptions
      (2) Genera1 Provisions
      (3) Specific Steps and Provisions
      (4) Adjustment of Baseline Nursing Home Need
  3. Nursing Home Bed Need Projection Method
    a. Summary
    b. Detailed Method
      (1) Assumptions
      (2) General Provisions
      (3) Specific Steps and Provisions
      (4) Adjustment of Baseline Nursing Home Need Projections
      (5) Data Sources and Methods
      (6) Definitions
  4. Hospital Bed Need Forecasting Method
    a. Introduction
    b. Summary
    c. Criteria and Standards for Evaluation and Use of Method
      (1) Definitions
      (2) General Princip1es
      (3) Criteria and Standards
    d. Specific Methods
      (1) Determination of Forecasting Policy
      (2) Methods of Overall Forecasts of Non-Psychiatric Bed Needs
      (3) Methods for Service Specific Forecasts
      (4) Short-Stay Psychiatric Bed Forecasting Method
    e. Guidelines for Adjusting Forecasts
      (1) General Adjustment Guidelines
      (2) Psychiatric Adjustments

APPENDICES

APPENDIX A: IN-HOSPITAL CANCER REHABILITATION PROGRAM
APPENDIX B: REQUIREMENTS FOR CONTINUING CARE RETIREMENT COMMUNITY PROJECTS
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Recommended Legislative Changes

Appendix C-1
Recommended Legislative Changes to RCW 70.38.015

Recommended Changes to RCW 70.38.015 (subsections 1, 2, 3, 4, 5, and 6)	Existing	Revised	New
It is declared to be the public policy of this state: (1) That a strategic health planning process, ~~to promote, maintain, and assure the health of all citizens in the state, to provide accessible health services, health manpower, health facilities, and other resources while controlling excessive increases in costs, and to recognize prevention as a high priority in health programs, is essential to the health, safety, and welfare of the people of the state. Health planning should be~~ responsive to changing health and social needs and conditions~~.~~, is essential to the health, safety, and welfare of the people of the state. Such a process shall be reviewed and updated biennially by a designated state agency or body;		X	
(a) To promote, maintain, and assure the health of all citizens in the state;		X*	
(b) To provide accessible health services through the maintenance of an adequate supply of health facilities and an adequate workforce~~, health manpower, health facilities, and other resources~~;		X	
(c) To ~~while~~ control~~ling~~ excessive increases in costs;		X*	
(d) To apply specific quality criteria and population health indicators;			X
(e) To recognize prevention as a high priority in health programs;			X
(f) To address periodic priority issues including disaster planning, public health threats, and public safety dilemmas;			X
(g) To coordinate efforts among state agencies including those tasked with facility, services, and professional provider licensure; state and federal reimbursement; health service utilization data systems; and others;			X
(h) To recognize the close interrelationship of health planning concerns and emphasize health care expenditure control, including cost-effectiveness and cost-benefit analysis; and			X
(i) To integrate criteria for evidence-based medicine;			X
(2) ~~Involvement in health planning from~~ That both consumers and providers throughout the state ~~should~~ shall be ~~encouraged~~ involved in this health planning process, outcomes of which shall be clearly articulated and available for public review and use;		X	
~~(2) That the development of health services and resources, including the construction, modernization, and conversion of health facilities, should be accomplished in a planned, orderly fashion, consistent with identified priorities and without unnecessary duplication or fragmentation;~~		X	
(3) That the certificate of need program is a component of a health planning regulatory process that:			X
(a) Contributes to state health plan and public policy goals that are: (i) Clearly articulated, and (ii) Regularly updated;			X

Recommended Changes to RCW 70.38.015 (subsections 1, 2, 3, 4, 5, and 6)	Existing	Revised	New
(b) Balances considerations of: (i) Access to quality care at a reasonable cost for all residents, (ii) Optimal use of existing health care resources, (iii) Fostering of expenditure control, and (iv) Elimination of unnecessary duplication of health care facilities and services;			X
(c) Supports improved health care outcomes by: (i) Basing decisions on the best available evidence and information, and (ii) Continuously monitoring compliance;			X
(d) Is accountable for maintaining the resources necessary for high quality decisions that are timely and consistent;			X
(e) Regularly evaluates the impact of capacity management on health service expenditures, access, quality, and innovation;			X
(f) Utilizes detailed criteria, standards, and need methodologies, both general and service/facility specific, that are updated at least biennially, after consultation with a technical advisory committee;			X
(g) Is conducted in a transparent and accountable manner;			X
(h) Provides request for-proposal invitations for certificate of need proposals based on service needs determined in the state health plan; and			X
(i) Use expedited and/or abbreviated cycles for applications that comply with the state health plan and have minimal impact on area health services;			X
(~~3~~4) That the development and ongoing maintenance of adequate health care information, statistics and projections of need for health facilities and services ~~is~~ are essential to effective health planning ~~and resources development;~~ at a minimum, available data shall support the review and monitoring of specified health care facilities and services regulated by the certificate of need program;		X	
(~~4~~5) That the development of ~~nonregulatory~~ other approaches to health care expenditure control ~~should~~ shall be considered, including the strengthening of ~~price~~ competition; and		X	
(~~5~~6) That strategic health planning ~~should~~ shall be concerned with ~~public health and health care financing, access, and quality, recognizing their close interrelationship and emphasizing cost control of health services, including cost effectiveness and cost benefit analysis~~ the stability of the health system, encompassing health care financing, quality, and the availability of information and services for all residents.		X	

*Technical corrections to improve readability without changing intent or meaning.

Appendix C-2
Recommended Legislative Changes to RCW 70.38.025

Recommended Changes to RCW 70.38.025 (subsections 6 and new)	Existing	Revised	New
(6) "Health care facility" means hospices, hospice care centers, hospitals, psychiatric hospitals, nursing homes, kidney disease treatment centers, ambulatory surgical facilities, ~~and~~ home health agencies, freestanding emergency departments, freestanding radiological service centers, diagnostic imaging centers and oncology (cancer) treatment centers, and includes such facilities when owned and operated by a political subdivision or instrumentality of the state and such other facilities as required by federal law and implementing regulations, but does not include any health facility or institution conducted by and for those who rely exclusively upon treatment by prayer or spiritual means in accordance with the creed or tenets of any well-recognized church or religious denomination, or any health facility or institution operated for the exclusive care of members of a convent as defined in RCW 84.36.800 or rectory, monastery, or other institution operated for the care of members of the clergy. In addition, the term does not include any nonprofit hospital: (a) Which is operated exclusively to provide health care services for children; (b) Which does not charge fees for such services; and (c) If not contrary to federal law as necessary to the receipt of federal funds by the state.		X	
(16) "Major medical equipment" means acquisition of gamma knives, positron emission tomography scanners (including PET/CT), linear accelerators (including cyber knives), and robotic surgery.			X
(17) "New health service" means cardiac surgery, and ambulatory surgery centers, regardless of owner or operator.			X

Appendix C-3
Recommended Legislative Changes to RCW 70.38.105

Recommended Changes to RCW 70.38.105 (subsections 4 and new)	Existing	Revised	New
(4) The following shall be subject to certificate of need review under this chapter;	X		
(a) The construction, development, or other establishment of a new health care facility;	X		
(b) The sale, purchase, or lease of part or all of any existing hospital as defined in RCW 70.38.025;	X		
(c) Any capital expenditure for the construction, renovation, or alteration of a nursing home which substantially changes the services of the facility after January 1, 1981, provided that the substantial changes in services are specified by the department in rule;	X		
(d) Any capital expenditure for the construction, renovation, or alteration of a nursing home which exceeds the expenditure minimum as defined by RCW 70.38.025. However, a capital expenditure which is not subject to certificate of need review under (a), (b), (c), or (e) of this subsection and which is solely for any one or more of the following is not subject to certificate of need review: (i) Communications and parking facilities; (ii) Mechanical, electrical, ventilation, heating, and air conditioning systems; (iii) Energy conservation systems; (iv) Repairs to, or the correction of, deficiencies in existing physical plant facilities which are necessary to maintain state licensure, however, other additional repairs, remodeling, or replacement projects that are not related to one or more deficiency citations and are not necessary to maintain state licensure are not exempt from certificate of need review except as otherwise permitted by (d)(vi) of this subsection or RCW 70.38.115(13); (v) Acquisition of equipment, including data processing equipment, which is not or will not be used in the direct provision of health services; (vi) Construction or renovation at an existing nursing home which involves physical plant facilities, including administrative, dining areas, kitchen, laundry, therapy areas, and support facilities, by an existing licensee who has operated the beds for at least one year; (vii) Acquisition of land; and (viii) Refinancing of existing debt;	X		
(e) A change in bed capacity of a health care facility which increases the total number of licensed beds or redistributes beds among acute care, nursing home care, and boarding home care if the bed redistribution is to be effective for a period in excess of six months, ~~or~~ a change in bed capacity of a rural health care facility licensed under RCW 70.175.100 that increases the total number of nursing home beds or redistributes beds from acute care or boarding home care to nursing home care if the bed redistribution is to be effective for a period in excess of six months, or a change in the types of services in a health care facility. A health care facility certified as a critical access hospital under 42 U.S.C. 1395i-4 may increase its total number of licensed beds to the total number of beds permitted under 42 U.S.C. 1395i-4 for acute care and may redistribute beds permitted under 42 U.S.C. 1395i-4 among acute care and nursing home care without being subject to certificate of need review. If there is a nursing home licensed under chapter 18.51 RCW within twenty-seven miles of the critical access hospital, the critical access hospital is subject to certificate of need review except for: (i) Critical access hospitals which had designated beds to provide nursing home care, in excess of five swing beds, prior to December 31, 2003; or (ii) Up to five swing beds. Critical access hospital beds not subject to certificate of need review under this subsection (4)(e) will not be counted as either acute care or nursing home care for certificate of need review purposes. If a health care facility ceases to be certified as a critical access hospital under 42 U.S.C. 1395i-4, the hospital may revert back to the type and number of licensed hospital beds as it had when it requested critical access hospital designation;		X	

Recommended Changes to RCW 70.38.105 (subsections 4 and new)	Existing	Revised	New
(f) Any new tertiary health services which are offered in or through a health care facility or rural health care facility licensed under RCW 70.175.100, and which were not offered on a regular basis by, in, or through such health care facility or rural health care facility within the twelve-month period prior to the time such services would be offered;	X		
(g) Any expenditure for the construction, renovation, or alteration of a nursing home or change in nursing home services in excess of the expenditure minimum made in preparation for any undertaking under subsection (4) of this section and any arrangement or commitment made for financing such undertaking. Expenditures of preparation shall include expenditures for architectural designs, plans, working drawings, and specifications. The department may issue certificates of need permitting predevelopment expenditures, only, without authorizing any subsequent undertaking with respect to which such predevelopment expenditures are made; ~~and~~		X*	
(h) Any increase in the number of dialysis stations in a kidney disease center~~.~~;		X*	
(i) Major medical equipment including gamma knives, positron emission tomography scanners (including PET/CT), linear accelerators (including cyber knives), and robotic surgery; and			X
(k) New health services including cardiac surgery, and ambulatory surgery centers, regardless of owner or operator.			X
(7) All health care facilities, major medical equipment and new health services that require a certificate of need shall be licensed or certified by state government.			X
(8) No state agency charged by statute to license or certify the facilities and services which require certificate of need review shall issue a license to or certify any such facility or service, or distinct part of such, that is developed without first obtaining a certificate of need.			X
(9) No agency of state government may appropriate or grant funds to or make payment of any funds to any person, health care facility or health care service which has not first obtained every certificate of need required.			X
(10) Certificate of need application fee structure, supplemented with other sources of revenue, to sufficiently cover the direct costs of certificate of need review monitoring and other related costs, shall be established.			X

*Technical corrections to improve readability without changing intent or meaning.

Appendix C-4
Recommended Legislative Changes to RCW 70.38.115

Recommended Changes to RCW 70.38.115 (subsections 1, 2, 4, and 5)	Existing	Revised	New
(1) Certificates of need shall be issued, denied, suspended, or revoked by the designee of the secretary in accord with the provisions of this chapter and rules of the department that develops review criteria and ~~which~~ establishes review procedures ~~and criteria for the certificate of need program~~.		X	
(2) Criteria for the review of certificate of need applications, except as provided in subsection (3) of this section for health maintenance organizations, shall include but not be limited to consideration of the following:	X		
(a) ~~The need that the population served or to be served by such services has for such services~~ Community need for the proposed services based on current utilization data and trends;		X	
(b) The availability of less costly or more effective alternative methods of providing such services;	X		
(c) The financial feasibility and the probable impact of the proposal on the cost of and charges for providing health services in the community to be served, including the impact on the current health system infrastructure and ability of existing providers to serve the underinsured and uninsured;		X	
(d) In the case of health services to be provided, (i) The availability of alternative uses of project resources for the provision of other health services, (ii) The extent to which such proposed services will be accessible to all residents of the area to be served, ~~and~~ (iii) The need for and the availability in the community of services and facilities for ~~osteopathic physicians and surgeons and allopathic physicians~~ health care providers and their patients, and (iv) The ~~department shall consider the application in terms of its~~ impact on existing and proposed institutional and other educational training programs ~~for doctors of osteopathic medicine and surgery and medicine~~ for health practitioners at the student, internship, and residency training levels;		X	
(e) In the case of a construction project, the costs and methods of the proposed construction, including the cost and methods of energy provision, and the probable impact of the ~~construction~~ project ~~reviewed~~ (i) On the cost of providing ~~health~~ services by the ~~person proposing such construction project~~ applicant, and (ii) On the cost ~~and charges to the public~~ of providing ~~health~~ services by other ~~persons~~ entities;		X	
(f) The special needs and circumstances of ~~osteopathic hospitals, nonallopathic services and~~ children's hospitals;		X	
(g) Improvements or innovations in the financing and delivery of health services ~~which~~ that foster cost containment and ~~serve to promote quality assurance and~~ cost effectiveness, and/or promote quality;		X	
(h) ~~In the case of~~ For proposed health services ~~proposed to be provided,~~ a comparison of the efficiency and appropriateness of the use of similar existing services and facilities ~~similar to those proposed~~;		X*	

Recommended Changes to RCW 70.38.115 (subsections 1, 2, 4, and 5)	Existing	Revised	New
(i) ~~In the case of~~ For existing services or facilities, the quality of care provided by such services or facilities in the past;		X*	
(j) In the case of hospitals ~~certificate of need applications,~~ whether the ~~hospital~~ applicant meets or exceeds the regional average level of charity care~~,~~ as determined by the secretary~~;~~, and whether the applicant has adopted policies consistent with the charity care and reporting requirement of RCW 70.170.060;		X*	
(k) ~~In the case of~~ For nursing home applications: (i) The availability of other nursing home beds in the planning area to be served; and (ii) The availability of other services in the community to be served. Data used to determine the availability of other services will include but not be limited to data provided by the department of social and health services~~.~~;		X*	
(l) For other certificate of need regulated services, whether the applicant will provide for charity care commensurate with current community standards for the service(s) to be offered;			X
(m) The availability of appropriate health care workers to deliver the proposed service; and			X
(n) Whether the applicant agrees to provide services to medicaid and medicare enrollees and agrees to not discriminate against medicaid and medicare enrollees based upon their coverage.			X
(4) ~~Until the final expiration of the state health plan as provided under RCW 70.38.919, the decision of the department on a~~ ~~c~~Certificate of need ~~application~~ decision shall be consistent with ~~the~~ a state health plan ~~in effect,~~ that is updated at least biennially, except in emergency circumstances ~~which~~ that pose a threat to the public health. The department ~~in making its final decision~~ may issue a conditional certificate of need if it finds that the project is justified only under specific circumstances. The conditions shall directly relate to the project being reviewed. The conditions may be ~~released~~ eliminated if it can be substantiated that the conditions are no longer valid and the ~~release~~ elimination of such conditions would be consistent with the purposes of this chapter.		X	
(5) Criteria adopted for review in accordance with subsection (2) of this section may vary according to the purpose for which the particular review is being conducted or the type of health service reviewed. Criteria, standards, and methods for determining need shall be reviewed and updated at least biennially after consultation with a technical advisory committee.		X	

*Technical corrections to improve readability without changing intent or meaning.

Appendix C-5
Recommended Legislative Changes to RCW 70.38.125

Recommended Changes to RCW 70.38.125 (subsections 3 and new)	Existing	Revised	New
(3) The department shall initially monitor the approved projects to assure conformance with certificates of need that have been issued until completion. Following completion of an approved project, the department shall continue to monitor compliance for five years. Rules and regulations adopted shall specify when changes in the project require reevaluation of the project. The department may require applicants to submit periodic progress reports on approved projects or other information as may be necessary to effectuate its monitoring responsibilities.		X	
(7) The department shall enforce penalties for non-compliance with provisions and conditions of the approved certificate of need application, using provisions to include, but not limited to, significant fines, revocation of certificate of need award, moratorium on future certificate of need applications for a specified period, and revocation of license, defined by rules and regulations.			X

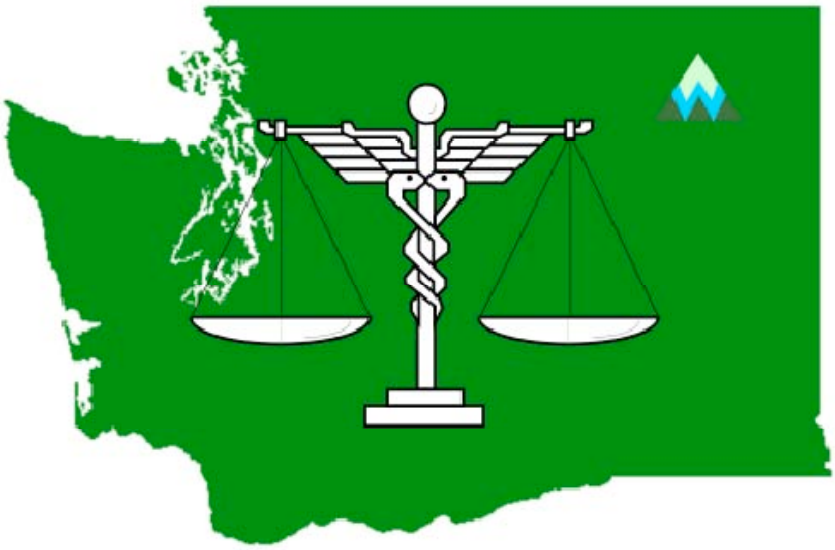
Appendix C-6
Recommended Legislative Changes to RCW 70.38.135

Recommended Changes to RCW 70.38.135 (subsections 3 and new)	Existing	Revised	New
(3) Upon review of recommendations, if any, from the board of health: (a) Promulgate rules under which health care facilities, major medical equipment and health service providers doing business within the state shall submit to the department such data defined in RCW 43.70.052 related to health and health care as the department finds necessary to the performance of its functions under this chapter including at least those facilities, equipment and services which require certificate of need review; (b) Promulgate rules pertaining to the maintenance and operation of medical facilities which receive federal assistance under the provisions of Title XVI; (c) Promulgate rules in implementation of the provisions of this chapter, including the establishment of procedures for public hearings for predecisions and post-decisions on applications for certificate of need; (d) Promulgate rules providing circumstances and procedures of expedited certificate of need review if there has not been a significant change in existing health facilities of the same type or in the need for such health facilities and services, and that comply with the state health plan and have minimal impact on area health services;		X	
(6) Provide invitations for CON proposals in response to service needs determined in the state health plan; and			X
(7) Utilize evidence-based health care criteria and standards consistent with the state health plan. State health plan criteria shall be updated at least biennially.			X

Appendix C-7
Recommended Legislative Changes to RCW 43.70.052

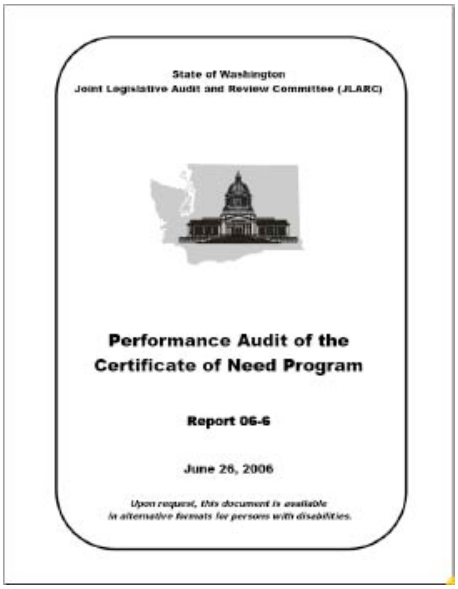
Recommended Changes to RCW 43.70.052 (new subsection)	Existing	Revised	New
(6) The department shall collect data as follows: (a) The data for certificate of need analysis and monitoring shall be a subset of a comprehensive data system for state health planning which includes improved data collection methodology and reporting consistent with technological advances; (b) There shall be ongoing certificate of need data collection acquired and reported by a state agency using consistent and reliable performance measures; (c) Data, as it relates to certificate of need reviewable services, shall include inpatient and outpatient utilization and outcomes information, and financial and utilization information related to charity care, quality, and cost regardless of the service location; (d) Data shall be publicly available for applicants and observers; and (e) Indications for quality and performance improvement that arise during the review process shall be reported to the state planning body and all other appropriate agencies.			X

Summary Excerpts from JLARC Report



Appendix D-1
Summary Excerpts from JLARC Report

At the June 28, 2006, CON Task Force meeting, the Joint Legislative Audit and Review Committee (JLARC) staff presented a report. It showed the recent results of the JLARC performance audit of the Department of Health's administration of the CON Program.



The Legislature, in ESSHB 1688, directed that JLARC perform this audit. The same legislation created the CON Task Force. The Legislature, in Section 3(3) of 1688, directed the Task Force to consider this report during the development of its recommendations on improving and updating the state's Certificate of Need Program.

The final JLARC report contained the following six recommendations.

Recommendations:

1. The Department of Health (DOH) should identify strategies for meeting established statutory timelines for Certificate of Need applications.
2. DOH should identify strategies to ensure that all statutory criteria for reviewing Certificate of Need applications are fully applied. The Department may also recommend amendments to statutory criteria, if necessary, to reflect the state's current health care system.
3. The Legislature should consider establishing consistent basic reporting requirements for all services and facilities that are subject to Certificate of Need review so that information related to each type of application will be readily available and reliable.
4. To ensure ongoing consistency in both the analysis and final decisions for Certificate of Need applications, DOH should perform regular and ongoing reviews of program staffs application reviews and issued decisions.
5. DOH should revise its monitoring practices to include completed projects, as appropriate, to ensure applicants' compliance with issued Certificates of Need in accordance with statute.
6. DOH should better use the Certificate of Need program's website to make more information on program activities and application forms available to the public.